SCIENTIFIC WORKING GROUP FOR THE ANALYSIS OF SEIZED DRUGS (SWGDRUG) RECOMMENDATIONS

RECOMMENDATIONS INCLUDE:

CODE OF PROFESSIONAL PRACTICE

EDUCATION and TRAINING

METHODS OF ANALYSIS

QUALITY ASSURANCE

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
COUNTERDRUG TECHNOLOGY ASSESMENT CENTER

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Foreword

This publication contains recommendations from the Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG). These recommendations are intended to assist forensic analysts and managers in the development of analytical techniques, protocols and policies. They are recognized to be minimum standards that may be modified to address unique jurisdictional requirements. SWGDRUG seeks to have these recommendations internationally accepted as the foundation for good laboratory practice. These recommendations encompass Code of Professional Practice, Education and Training, Methods of Analysis and Quality Assurance. The SWGDRUG Core Committee strongly urges the adoption of these recommendations by any laboratory involved in the analysis of seized drugs.

Since 1997, SWGDRUG has been working to provide useful and practical minimum recommendations for the analysis of seized drugs. SWGDRUG recognizes that over time these recommendations may need to be updated as a result of advances in technology, changes in accreditation requirements and/or the emergence of new requirements. To this end, SWGDRUG relies heavily on the input of the forensic community to ensure that all recommendations remain useful and current. This synergetic approach is a key component of the SWGDRUG process. I encourage everyone to continue supporting the mission of SWGDRUG.

Finally, as the Chair of SWGDRUG, I would be remiss if I did not single out several individuals without whom SWGDRUG would not exist. Benjamin A. Perillo conceived this working group and made it a reality. And former Chairs of SWGDRUG, Thomas J. Janovsky, Nelson A. Santos, and Scott R. Oulton promoted and enhanced SWGDRUG's prominence in the forensic community. I also would like to recognize previous Vice-Chair Linda C. Jackson and current Vice-Chair Christian Matchett, for their many years of continuous dedication to SWGDRUG.

I would also like to make special mention to the Drug Enforcement Administration, the Office of National Drug Control Policy and the National Institute of Standards and Technology, which over the years have provided the financial resources for SWGDRUG to operate.

Sandra E. Rodriguez-Cruz

Introduction

SWGDRUG is comprised of a core committee of approximately 20 members from around the world.

Mission Statement:

SWGDRUG works to improve the quality of the forensic examination of seized drugs and to respond to the needs of the forensic community by supporting the development of internationally accepted minimum standards, identifying best practices within the international community, and providing resources to help laboratories meet these standards.

SWGDRUG seeks to achieve this mission through the following objectives:

- specifying requirements for practitioners' knowledge, skills and abilities,
- promoting professional development,
- providing a means of information exchange within the forensic science community,
- promoting ethical standards of practitioners,
- recommending minimum standards for examinations and reporting,
- providing resources and tools,
- establishing quality assurance requirements,
- considering relevant international standards, and
- seeking international acceptance of SWGDRUG recommendations.

Drug abuse and trafficking in controlled substances are global problems, and law enforcement has looked to international solutions for these problems. In 1997 the U.S. Drug Enforcement Administration (DEA) and the Office of National Drug Control Policy (ONDCP) co-sponsored the formation of the Technical Working Group for the Analysis of Seized Drugs (TWGDRUG). Forensic scientists from the United States, England, Canada, Australia, Japan, Germany and the Netherlands, as well as representatives of the United Nations, several international forensic organizations and academia were invited to meet in Washington, DC. This group, with input from around the world, developed educational and professional development recommendations for forensic practitioners. They also developed quality assurance and identification recommendations for seized drugs. The name Scientific Working Group for the Analysis of Seized Drugs was adopted in 1999.

SWGDRUG has received input from many members of the forensic community in its document development process. It has used various methods of communication including its website (www.swgdrug.org), presentations at numerous local, national and international meetings, and personal contacts. Following each meeting of the Core Committee, updates are published and distributed.

SWGDRUG seeks and considers comments from the forensic science community on all its proposals. In order for a recommendation to be adopted, there are specific procedures that must be met. Please refer to the SWGDRUG's bylaws, which can be found at www.swgdrug.org/bylaws.htm for additional details. In addition, SWGDRUG has submitted its recommendations to ASTM International, a standards developing organization, resulting in seven published standards:

E2326	Standard Practice for Education and Training for Seized-Drug Analysts
E2327	Standard Practice for Quality Assurance of Laboratories Performing Seized-Drug Analysis
E2329	Standard Practice for Identification of Seized Drugs
E2548	Standard Guide for Sampling Seized Drugs for Qualitative and Quantitative Analysis
E2549	Standard Practice for Validation of Seized-Drug Analytical Methods
E2764	Standard Practice for Uncertainty Assessment in the Context of Seized-Drug Analysis
E2882	Standard Guide for Analysis of Clandestine Drug Laboratory Evidence

In August 2022 the leadership of SWGDRUG was transferred to Sandra E. Rodriguez-Cruz, Chair and Jaclyn Iera, Secretariat. The various sub-committees continue to research and develop proposals for additional recommendations with several members completing their service to the group and others replacing them by invitation.
The following list includes those persons who have rendered service as members of the core committee over the years. Current core committee members are indicated in bold text. A list of current members is also available on the SWGDRUG website.

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***** Past Chair
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# Past Secretariat

PART I

A CODE OF PROFESSIONAL PRACTICE FOR DRUG ANALYSTS

PREFACE

This Code of Professional Practice has been written specifically for analysts. However, it is important that their managers and the technicians and others who assist them in their work are equally aware of its provisions, and they support the analyst in adhering to these. Where appropriate, the provisions are also equally applicable to the technicians in the approach to their own work.

I.1 Introduction

I.1.1 A Code of Professional Practice is intended to provide the framework of ethical values and scientific and legal obligations within which the analyst should operate. Details are also usually provided on how alleged breaches of the Code will be investigated, what sanctions are available and how appeals should be pursued.

I.1.2 A Code of Professional Practice is essential to analysts and their managers in helping them carry out their duties in a proper manner and in making appropriate decisions when questions of ethics arise.

I.1.3 A Code of Professional Practice that is enforced and publicly available is also a powerful means of demonstrating the professional expectations of analysts and the reliability of their findings to others in the criminal justice system and the public at large.

I.1.4 SWGDRUG recommends that all employers of analysts develop a Code of Professional Practice and the means of dealing with breaches of the Code.

I.1.5 SWGDRUG further recommends that all Codes of Professional Practice for analysts should include, as a minimum, provisions relating to their professional conduct, their casework and the reporting of their results, as provided in Section 2. For further information, see Supplemental Document SD-1 (Examples for Part I - A Code of Professional Practice for Drug Analysts).

I.2 Code of professional practice

I.2.1 Professional conduct

Analysts shall:

a) act with honesty, integrity and objectivity;

b) work only within the bounds of their professional competence;

c) take reasonable steps to maintain their competence;

d) recognize that their overriding duty is to criminal justice;

e) declare to their employer any prior contact or personal involvement, which may give rise to conflict of interest, real or perceived;

f) declare to their employer or other appropriate authority any pressure intended to influence the result of an examination.

I.2.2 Casework

Analysts shall:

a) strive to demonstrate that the integrity and security of evidential materials and the information derived from their analysis have been maintained while in their possession;

b) strive to have a clear understanding of what the customer needs and all the necessary information, relevant evidential materials and facilities available to reach a meaningful conclusion in an appropriate timeframe;

c) employ an appropriate analytical approach, using the facilities available;

d) make and retain full, contemporaneous, clear and accurate records of all examinations and tests conducted, and conclusions drawn, in sufficient detail to allow meaningful review and assessment of the conclusions by an independent person competent in the field;

e) accept responsibility for all casework done by themselves and under their direction;

f) conduct all professional activities in a way that protects the health and safety of themselves, co-workers, the public and the environment.

I.2.3 Reporting

Analysts shall:

a) present advice and testimony, whether written or oral, in an objective manner;

b) be prepared to reconsider and, if necessary, change their conclusions, advice or testimony in light of new information or developments, and take the initiative in informing their employer and customers promptly of any such changes that need to be made;

c) take appropriate action if there is potential for, or there has been, a miscarriage of justice due to new circumstances that have come to light, incompetent practice or malpractice;

d) preserve customer confidentiality unless officially authorized to do otherwise.

PART II

EDUCATION,TRAINING, AND CONTINUING PROFESSIONAL DEVELOPMENT

II.1 Introduction

Part II recommends minimum education, training and experience for analysts practicing in laboratories that conduct seized drug analyses. It describes the types of activities necessary to continue professional development and reference literature required in laboratories where they practice.

II.1.1 Recommendations listed in Part II are intended to apply to any analyst who:

a) independently has access to unsealed evidential material in order to remove samples for examination;

b) examines and analyzes seized drugs or related materials, or directs such examinations to be done; and

c) as a consequence of such examinations, signs reports for court or investigative purposes.

II.2 Education and experience for analysts

All new analysts shall have at least a bachelor's degree or equivalent (generally, a three to four year post-secondary degree) in a natural/physical science. The individual shall have:

- theoretical knowledge in foundational chemistry concepts, organic chemistry, and analytical chemistry, including quantitative analysis and instrumental analysis; and
- practical knowledge from in-person laboratory classes with experiences such as the preparation of solutions, reagents, chemical samples, etc., as well as exposure to analytical equipment and analysis of resulting data.

NOTE: Virtual laboratory exercises should not be a replacement for practical, in-person training.

Additional relevant experience is encouraged and shall be considered. Examples include:

- coursework in statistics and ethics
- oral and written communication
- research
- internship or work experiences

II.3 Initial training requirements

These minimum requirements allow individual laboratories to structure their training program to meet their needs as it relates to type of casework encountered, analytical techniques, available instrumentation and level of preparedness of trainees.

II.3.1 There shall be a documented training program, approved by laboratory management that focuses on the development of theoretical and practical knowledge, skills and abilities necessary to examine seized drug samples and related materials. The training program shall include the following:

a) documented standards of performance and a plan for assessing theoretical and practical competency against these standards (e.g., written and oral examinations, critical reviews, analysis of unknown samples and mock casework per topic area);

b) a training syllabus providing descriptions of the required knowledge and skills in specific topic areas in which the analyst is to be trained, milestones of achievement, and methods of testing or evaluating competency;

c) a period of supervised casework representative of the type the analyst will be required to perform;

d) a verification document demonstrating that the analyst has achieved the required competence.

II.3.2 Topic areas in the training program shall include, as a minimum, the following:

- relevant background information on drugs of abuse (e.g., status of control and chemical and physical characteristics)
- techniques, methodologies and instrumentation utilized in the examination of seized drug samples and related materials
- quality assurance
- ethics
- expert/court testimony and legal requirements
- laboratory policy and procedures (e.g., sampling, uncertainty, evidence handling, safety and security) as they relate to the examination of seized drug samples and related materials.

II.3.3 SWGDRUG endorses the ENFSI Drug Working Group document "Education and Training Outline for Forensic Drug Practitioners" and recommends its use in the development of training programs.

II.3.4 An individual qualified to provide instruction shall have demonstrated competence in the subject area and in the delivery of training.

II.4 Continuing professional development

All analysts have an ongoing responsibility to remain current in their field. In addition, laboratories shall provide support and opportunities for continuing professional development. Minimum continuing professional development requirements for a laboratory analyst are:

II.4.1 Twenty hours of training every year.

II.4.2 Training shall be relevant to the analyst's work assignment. Professional development may include training related to ancillary duty assignments and supervision/management responsibilities.

II.4.3 Training shall be documented.

II.4.4 Training can be in-person interaction with an instructor, distance learning, self-directed or computer based. Training can include, but is not limited to the following:

- chemistry or instrumental courses taught at the post-secondary educational level
- in-service training, conducted by the employer or by external providers
- current literature review
- instrument operation or maintenance training, provided in-house or by vendors
- participation in relevant scientific meetings or conferences (e.g., delivering an oral or poster presentation, attending a workshop, providing reports on conferences, etc.).

II.5 References and documents

The following references and documents shall be available and accessible to analysts.

a) college/university level textbooks for reference to theory and practice in key subject areas, e.g., general chemistry, organic chemistry and analytical chemistry

b) reference literature containing physical, chemical and analytical data. Such references include the *Merck Index*, *Clarke's Analysis of Drugs and Poisons*, laboratory manuals of the UNODC, in-house produced spectra and published standard spectra, (e.g., Mills and Roberson's *Instrumental Data For Drug Analysis*, or compendia from Pfleger or Wiley)

c) operation and maintenance manuals for each analytical instrument

d) relevant periodicals (e.g., *Journal of Forensic Sciences*, *Forensic Science International*, *The Canadian Society of Forensic Science Journal*, *Science & Justice*, *Drug Testing and Analysis*, *Forensic Chemistry*)

e) laboratory quality manual, standard operating procedures, and method validation and verification documents

f) relevant jurisdictional legislation (e.g., statutes and case law relating to controlled substances, and health and safety legislation)

PART III A

METHODS OF ANALYSIS/SAMPLING SEIZED DRUGS FOR QUALITATIVE ANALYSIS

IIIA.1 Introduction

This document addresses minimum recommendations for sampling of seized drugs for qualitative analysis.

NOTE For the purpose of this document the use of the term “statistical” refers to “probability-based.”

IIIA.1.1 The principal purpose of sampling in the context of this recommendation is to answer relevant questions about a population by examination of a portion of the population (e.g., What is the net weight of the population? What portion of the units of a population can be said to contain a given drug at a given level of confidence?)

IIIA.1.2 By developing a sampling strategy and implementing appropriate sampling schemes, as illustrated in Figure 1, a laboratory will minimize the total number of required analytical determinations, while assuring that all relevant legal and scientific requirements are met.

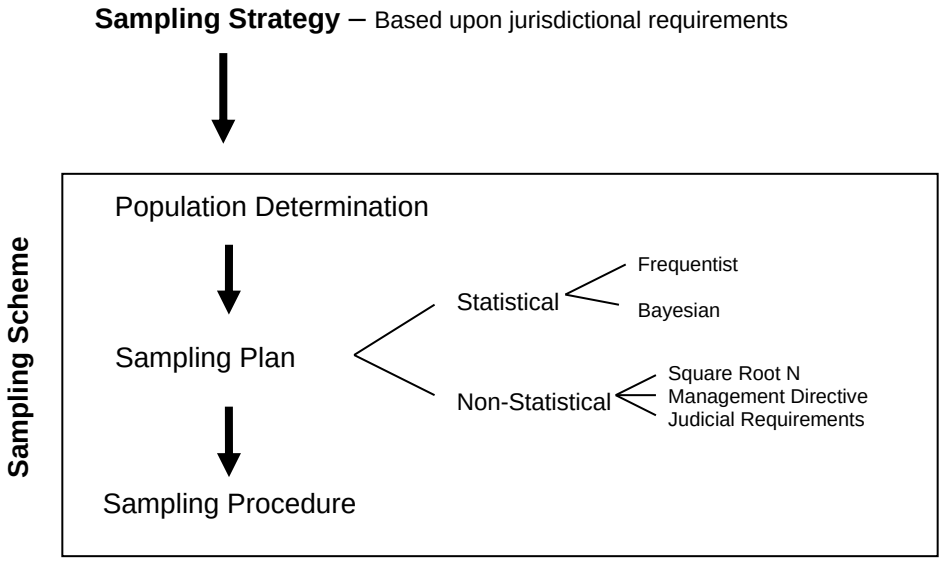

Figure 1: Relationship of the Various Levels Required in Sampling

IIIA.2 Sampling strategy

An appropriate sampling strategy is highly dependent on the purpose of the investigation, the customer's request, and the anticipated use of the results. Laws and legal practices form the foundation of most strategies and shall be taken into account when designing a sampling scheme. Therefore, specific sampling strategies are not defined in this document.

IIIA.2.1 The laboratory has the responsibility to develop its own strategies consistent with these recommendations. SWGDRUG recommends attention to the following key points:

IIIA.2.1.1 Sampling may be statistical or non-statistical.

IIIA.2.1.1.1 In many cases, a non-statistical approach may suffice. The sampling plan shall provide an adequate basis for answering questions of applicable law (e.g., Is there a drug present in the population? Are statutory enhancement levels satisfied by the analysis of a specified number of units?)

IIIA.2.1.1.2 If an inference about the whole population is to be drawn from a sample, then the plan shall be either statistically based or have an appropriate statistical analysis completed and limits of the inference shall be documented.

IIIA.2.1.2 Each selected sample shall be analyzed to meet the SWGDRUG minimum recommendations for forensic drug identification (see Part III B – Analytical Scheme for Identification of Drugs or Chemicals) if statistical inferences are to be made about the chemical identity of a population.

IIIA.3 Sampling scheme

The sampling scheme is an overall approach which includes population determination, selection of the sampling plan and procedure and, when appropriate, sample reduction prior to analysis (Figure 2).

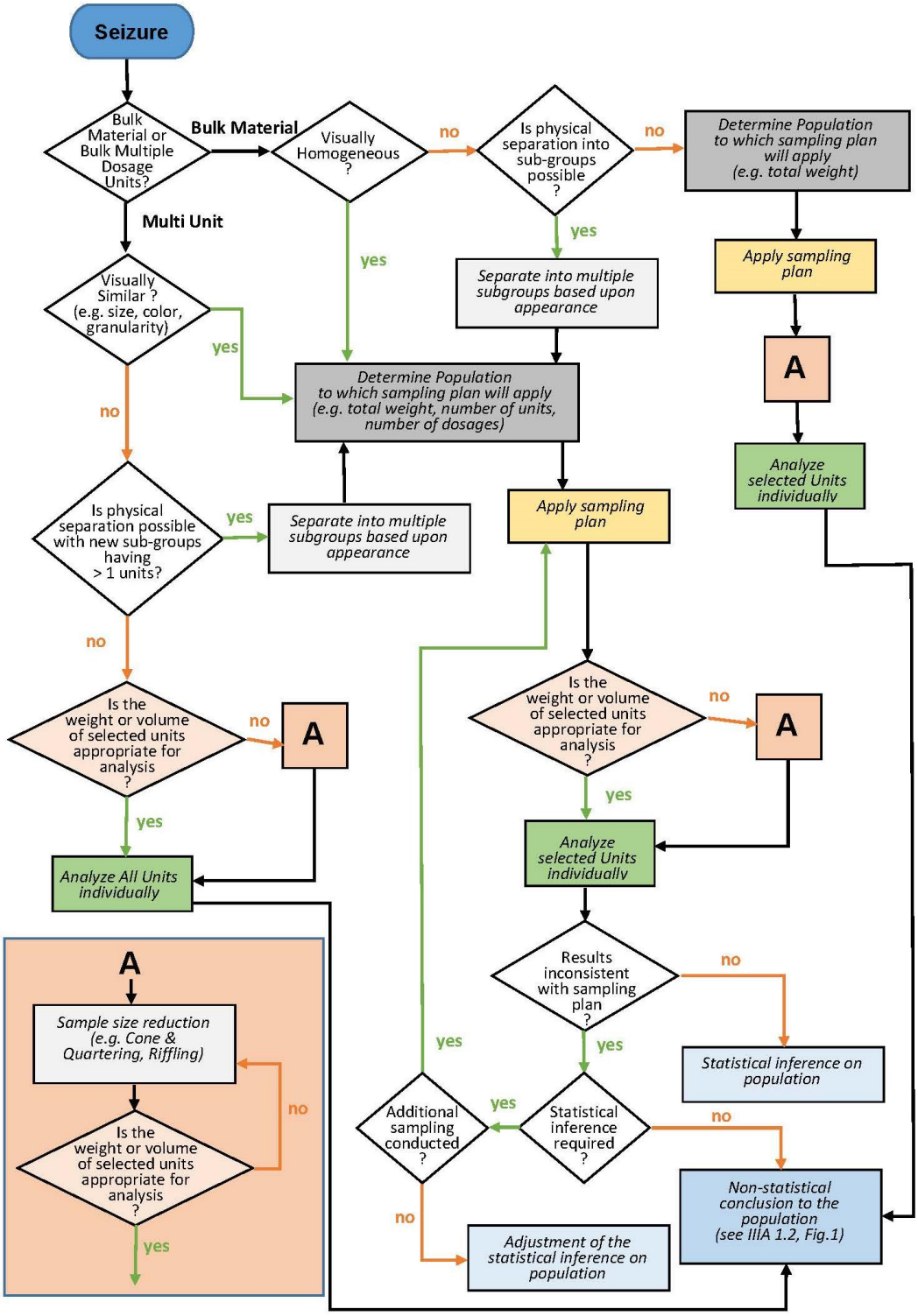

Figure 2: Example of a Sampling Scheme - A Decision Flowchart

IIIA.3.1 Population determination

IIIA.3.1.1 The population determination shall take into account all typical forms and quantities in which exhibits may appear.

IIIA.3.1.2 A population can consist of a single unit or multiple units.

IIIA.3.1.3 A multiple unit population shall consist of items, which are similar in relevant visual characteristics (size, color, shape, etc.).

IIIA.3.2 Sampling plan

There are numerous sampling plans used in the forensic analysis of drugs that are applicable to single and multiple unit populations.

IIIA.3.2.1 When a single unit or bulk population is to be analyzed, the issue of homogeneity shall be addressed within the sampling plan.

IIIA.3.2.1.1 One sample is sufficient if the bulk material is homogeneous, or if it is made so by the analyst.

IIIA.3.2.1.2 If the bulk material is not homogeneous, several samples from different locations may be necessary to ensure that the test results are representative of the bulk material and to avoid false negative results.

IIIA.3.2.2 For a multiple unit population, the sampling plan may be statistical or non-statistical.

IIIA.3.2.2.1 Statistical approaches are applicable when inferences are made about the whole population. For example:

a) The probability that a given percentage of the population contains the drug of interest or is positive for a given characteristic.

b) The total net weight of the population is to be extrapolated from the average weight of individual sample units.

Published examples are provided below:

- Frequentist
  - Hypergeometric
    - Frank *et al*., *Journal of Forensic Sciences*, 1991, 36(2) 350-357
    - *Guidelines on Sampling of Illicit Drugs for Qualitative Analysis*, European Network of Forensic Science Institutes (ENFSI), 2016, www.enfsi.eu
    - American Society for Testing and Materials (ASTM) E-2334
  - Other probability-based approaches
    - ASTM E105 "Standard Practice for Probability Sampling of Materials"
    - ASTM E122 "Standard Practice for Calculating Sample Size to Estimate, With a Specified Tolerable Error, the Average for a Characteristic of a Lot or Process"
    - *Guidelines on Sampling of Illicit Drugs for Qualitative Analysis*, ENFSI, 2016, www.enfsi.eu
- Bayesian
  - Coulson *et al., Journal of Forensic Sciences*, 2001, 46(6) 1456-1461
  - *Guidelines on Sampling of Illicit Drugs for Qualitative Analysis*, ENFSI, 2016, www.enfsi.eu

IIIA.3.2.2.2 Non-statistical approaches are appropriate if no inference is to be made about the whole population.

IIIA.3.2.2.3 A non-statistical sampling approach may allow an inference on the population. If the population has been randomly sampled, the data may allow an inference to be drawn by:

- determining and reporting a confidence interval for an inferred population parameter (e.g. weight or tablet count).

- Retrospectively using the results in a statistical model and determining the resulting probabilities and level of confidence.

IIIA.3.2.2.4 If a non-random sampling plan has been used, then no inference shall be made.

Examples of non-statistical approaches are:

- The “square root” method
  - *Recommended Methods for Testing Opium, Morphine and Heroin: Manual for Use by National Drug Testing Laboratories*, United Nations Office on Drugs and Crime, 1998
- *Guidelines on Sampling of Illicit Drugs for Qualitative Analysis*, ENFSI, 2016, www.enfsi.eu
- Selection of a single unit from a multiple unit population. This may be appropriate under certain circumstances (e.g., management directives, legislative and/or judicial requirements).

IIIA.3.3 Sampling procedure

IIIA.3.3.1 Establish the procedure for selecting the number of units that will comprise the sample.

IIIA.3.3.1.1 For non-statistical approaches select a sample appropriate for the analytical objectives.

IIIA.3.3.1.2 For statistical approaches, a random sampling shall be conducted.

IIIA.3.3.2 Select a random sample.

IIIA.3.3.2.1 A random sample is one selected without bias. Computer generated random numbers or random number tables are commonly employed for such tasks and these should be included in the sampling plan.

IIIA.3.3.2.2 Random sampling of items using random number tables may not be practical in all cases. In these instances, an alternate sampling plan shall be designed and documented to approach random selection. A

practical solution involves a “black box” method, which refers to one that will prevent the sampler from consciously selecting a specific item from the population (e.g., all units are placed in a box and the samples for testing are selected without bias). Random sampling is discussed in the following references:

- ASTM E105 “Standard Practice for Probability Sampling of Materials”
- *Guidelines on Sampling of Illicit Drugs for Qualitative Analysis*, ENFSI, 2016, “Chapter 4: Arbitrary Sampling”, pages 15-16; www.enfsi.eu

IIIA.3.4 Sample reduction

Sample reduction may be applied in cases where the weight or volume of the selected units is too large for laboratory analysis (Figure 2, insert A).

IIIA.4 Analysis

IIIA.4.1 Statistically selected sample(s)

If statistical inferences are to be made about the chemical identity of a population, each selected sample shall be analyzed to meet the SWGDRUG minimum recommendations for forensic drug identification (see Part III B – Analytical Scheme for Identification of Drugs or Chemicals). If results are not consistent in one or more of the selected samples and the sampling plan does not account for said inconsistent results, the original statistical hypothesis is invalid. Statistical inferences, if any, must be revised to address the implications of such results.

IIIA.4.2 Non-statistically selected sample(s)

SWGDRUG minimum recommendations for forensic drug identification (see Part III B – Analytical Scheme for Identification of Drugs or Chemicals) shall be applied to at least one unit of the sample.

IIIA.5 Documentation

Inferences drawn from the application of the sampling plan and subsequent analyses shall be documented.

IIIA.6 Reporting

Sampling information shall be included in reports (see Part IV A – Report Writing).

IIIA.6.1 Statistically selected sample(s)

Reporting statistical inferences for a population is acceptable when testing is performed on the statistically selected units as stated in Section 4.1 above. The language in the report must make it clear to the reader that the results are based on a sampling plan.

IIIA.6.2 Non-statistically selected sample(s)

The language in the report must make it clear to the reader that the results apply to only the tested units. For example, 2 of 100 bags were analyzed and found to contain Cocaine.

PART III B

METHODS OF ANALYSIS/ANALYTICAL SCHEME FOR IDENTIFICATION OF DRUGS OR CHEMICALS

The purpose of Part III B is to recommend minimum requirements for the forensic identification of seized drugs or chemicals. A reliable and scientifically supported identification of a drug or chemical depends on the use of an appropriate analytical scheme by competent analysts in a quality-controlled process. Part III B addresses the overall selection of techniques upon which validated methods and procedures are applied in the laboratory.

IIIB.1 Introduction

An analytical scheme is a combination of selected techniques used to reach a scientifically supported conclusion. For example, the scheme required to answer the question “is methamphetamine present?” would be different from the scheme needed to answer the question “is the isomer l-methamphetamine present?”

IIIB.2 Elements of an Analytical Scheme

IIIB.2.1 Techniques incorporated within the analytical scheme can be classified into three categories based upon the level of selectivity they achieve (Figure 1).

IIIB.2.2 An appropriate analytical scheme shall achieve a sufficient level of selectivity to enable a scientifically supported conclusion relevant to the jurisdiction and laboratory protocols.

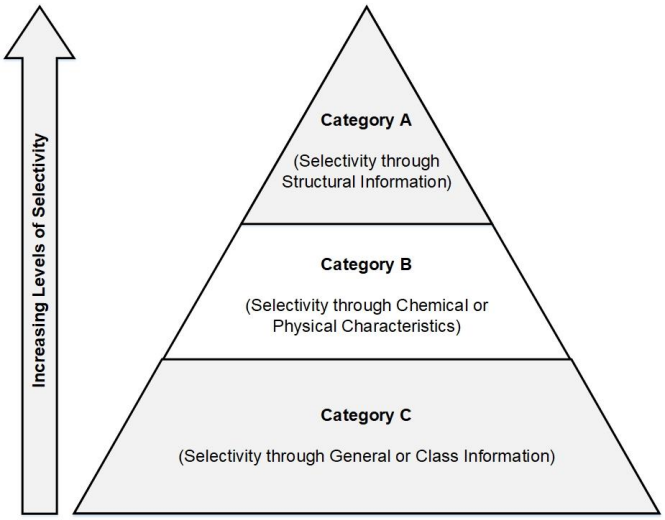

Figure 1 – Levels of Selectivity

IIIB.2.3 Table 1 presents techniques that may be incorporated within an analytical scheme for the identification of drugs or chemicals. Techniques are grouped according to their highest potential level of selectivity. When a technique is not used to its full potential, the analyst shall consider what level of selectivity the data achieved. Category A techniques provide the highest level of selectivity through structural information, Category B techniques provide an intermediate to high level of selectivity through physical / chemical characteristics without structural information, and Category C techniques achieve a low level of selectivity but provide general or class information.

Table 1 – Categories of Analytical Techniques[1]

Category A (Selectivity through Structural Information)	Infrared Spectroscopy
	Mass Spectrometry
	Nuclear Magnetic Resonance Spectroscopy
	Raman Spectroscopy
	X-ray Diffractometry[2]
Category B (Selectivity through Chemical and Physical Characteristics)	Capillary Electrophoresis
	Gas Chromatography
	Ion Mobility Spectrometry
	Liquid Chromatography
	Microcrystalline Tests
	Supercritical Fluid Chromatography
	Thin Layer Chromatography
	Ultraviolet/Visible Spectroscopy[3]
	Macroscopic Examination (Cannabis only)
	Microscopic Examination (Cannabis only)
Category C (Selectivity through General or Class Information)	Color Tests
	Fluorescence Spectroscopy
	Immunoassay
	Melting Point
	Pharmaceutical Identifiers[4]

[1] Techniques within categories are presented in no particular order or ranking.

[2] X-ray Diffractometry provides crystallographic structural information, rather than molecular structural information.

[3] Ultraviolet/Visible Spectroscopy, when used with a wavelength range, has been placed in Category B.

[4] Pharmaceutical Identifiers may provide a high degree of selectivity, but due to the potential for counterfeits, the technique has been placed in Category C.

IIIB.2.4 Since the identification of a drug or chemical can be achieved using a variety of techniques in different combinations, the analysts must design their analytical scheme based on suitable techniques and the requirements of their jurisdiction; see Supplemental Document SD-7 (Construction of an Analytical Scheme) for examples.

IIIB.2.5 When building an analytical scheme, the laboratory shall include appropriate quality practices (see Part IV A – General Practices). Relevant limitations of the scheme shall be documented and reported, as required. (see Part IV C – Uncertainty).

IIIB.2.6 An analytical scheme shall be comprised of validated methods that are appropriate for the analyte.

IIIB.2.7 It is the responsibility of the laboratory's management to provide adequate instrumentation / equipment to allow the appropriate combination of analytical techniques that achieves identification and meets the requirements of its jurisdiction.

IIIB.3 Minimum Requirements for an Analytical Scheme for Drugs and Chemicals

IIIB.3.1 When a Category A technique is incorporated into an analytical scheme, at least one other technique, which exploits different chemical or physical properties of the analyte, (from either Category A, B or C) shall be used to support the identification.

IIIB.3.1.1 A technique is considered Category A when the data obtained provide structural information, a high level of selectivity, and are reviewable.

IIIB.3.1.2 A Category A technique may not provide sufficient selectivity when:

IIIB.3.1.2.1 The mode of operation or the level of resolution of the technique limits the ability to distinguish the analyte from structurally similar or related compounds;

IIIB.3.1.2.2 The properties or complexity of the sample limit the ability to distinguish the analyte of interest; or

IIIB.3.1.2.3 The quantity of the sample or concentration of the analyte is limited.

IIIB.3.2 When a Category A technique is not used, at least three separate techniques shall be employed; two shall be from Category B, the combination of which provides a high degree of selectivity. The third technique (either Category B or C) is required to support the identification.

IIIB.3.2.1 A high degree of selectivity is achieved when the two chosen Category B techniques exploit different chemical or physical properties of the analytes (e.g., GC and LC).

IIIB.3.3 For the results of the techniques within the analytical scheme to be considered of value towards the identification of the analyte, the test results must be positive, meet all quality control requirements, and achieve the selectivity required.

IIIB.3.3.1 In circumstances where limitations are observed, the technique may still form part of an analytical scheme provided the results are positive and the limitations are addressed through the use of another suitable technique within the scheme, which achieves the overall level of selectivity required for identification.

IIIB.3.3.2 A result is considered positive when it fulfils the laboratory-defined acceptance criteria for the test. Tests shall include comparisons using a suitable reference material, external reference data, or include structural elucidation (see Part IV A – General Practice, section 6.1.6).

IIIB.3.3.3 When a positive test result does not achieve the level of selectivity required, additional technique(s) may be necessary within the analytical scheme.

IIIB.3.3.4 While negative or inconclusive results may provide useful information, they do not contribute towards establishing the identification of the drug or chemical.

IIIB.3.4 A hyphenated technique (e.g. gas chromatography-mass spectrometry, liquid chromatography-ultraviolet/visible spectroscopy) may be considered as two separate techniques within the analytical

scheme provided the criteria for positive results are fulfilled for both techniques.

IIIB.3.4.1 When using a hyphenated technique, the analyst is not precluded from using only one of the two results produced, as long as the results are not inconsistent.

IIIB.3.4.2 When only two tests are performed and the results originate from the use of a hyphenated technique, quality practices such as those described in Part III B.5.2 are required.

IIIB.3.5 The analytical scheme provides a scientifically supported conclusion when each technique achieves the level of selectivity required and the positive test results corroborate each other.

IIIB.3.6 Relevant limitations of the scheme shall be documented and reported, as required.

IIIB.4 Minimum Requirements for an Analytical Scheme for Botanicals

IIIB.4.1 Identifications and reporting of chemical components contained in botanicals (e.g., mescaline, opiates, psilocin, THC) shall rely on principles described above (Part III B.3) for building an analytical scheme.

IIIB.4.2 For herbal cannabis, macroscopic and microscopic examinations will be considered as different techniques from Category B when observations include documented details of botanical features. Laboratories shall define the acceptance criteria for these botanical features for each examination.

IIIB.4.3 For jurisdictions that require exhibits of cannabis to be further differentiated based on a particular cannabinoid concentration (e.g., hemp versus marijuana), the analytical scheme shall include an assessment of the cannabinoid level.

IIIB.4.4 When the jurisdiction allows, cannabis and other botanical material may be identified by botanists utilizing morphological characteristics alone provided sufficient botanical features appropriate for identification are observed and documented. Such examinations shall be made only by analysts competent in botanical identifications. In

this context, competency exclusively applies to those examiners recognized as professional botanists or those who are appropriately trained in botanical identification.

IIIB.5 Quality Practices

IIIB.5.1 All Category A and B techniques shall have data that are reviewable to allow an independent interpretation of the result. Examples of reviewable data for various techniques include:

- instrumental techniques – spectra, chromatograms, or images
- TLC – images, photocopies (color, when possible) or contemporaneous documented peer-reviewed notes
- microcrystalline tests – images or contemporaneous documented peer-reviewed notes
- cannabis and botanical materials – contemporaneous detailed descriptions of morphological characteristics

IIIB.5.2 The laboratory shall employ a number of quality practices to ensure the results correspond to the sample tested. Examples of appropriate measures include:

- removing two aliquots from the sample and testing them independently
- using procedural blanks
- using sample identification procedures such as bar-coding and witness checks
- analyzing/opening one sample at a time

PART III C

METHODS OF ANALYSIS/CLANDESTINE DRUG LABORATORY EVIDENCE

These recommendations are intended to be used in conjunction with the general requirements for the analysis of seized drugs. This document provides guidance on the chemical analysis of items and samples related to suspected clandestine drug laboratories. It does not address scene attendance or scene processing. This document provides general recommendations for the analysis of clandestine laboratory evidence and is not a substitute for detailed and validated laboratory policies and technical procedures.

IIIC.1 Introduction

IIIC.1.1 SWGDRUG considers an understanding of clandestine laboratory synthetic routes and the techniques used in the analysis of related samples to be fundamental to the interpretation and reporting of results. This understanding assures that results and conclusions from methods are reliable and analytical schemes are fit for purpose.

IIIC.1.2 The qualitative and quantitative analyses of clandestine laboratory evidence can require different approaches relative to routine seized drug analyses. Analysts shall understand the limitations of the procedures used in their qualitative and quantitative analyses.

IIIC.1.3 Laboratory management shall ensure that clandestine laboratory synthesis and analysis training be provided through relevant procedures, literature, and practical experience. Practical experience typically includes production, sampling and analysis of clandestine laboratory training samples.

IIIC.1.4 Laboratory management shall ensure that chemical safety and hygiene plans address and mitigate hazards associated with clandestine laboratory evidence.

IIIC.1.5 Laboratory management shall consider customer / local requirements which influence the application of these recommendations.

IIIC.2 Safety

IIIC.2.1 Many items seized at clandestine laboratories may be intrinsically dangerous. These may include items of unknown composition and chemicals that have not been fully characterized and whose specific hazards are not known. Therefore, caution must be exercised and routine safety protocols may not be sufficient.

IIIC.2.2 The following are required in addition to the routine laboratory safety program in place for the analysis of seized drugs (see Part IV A – Health and Safety):

- safety procedures and ~~in~~ the use of safety and protective equipment for all staff responsible for handling items
- protective breathing equipment
- listings of the relevant hazards (e.g. SDS) associated with components commonly found at clandestine laboratory sites and knowing what they mean
- accident prevention, emergency response procedures, and incident reporting protocols

IIIC.2.3 The handling, analysis, and storage of items seized from clandestine laboratories require additional procedures, facilities and equipment. (see Part IV A – Physical Plant): Examples are:

- specialized ventilation equipment (e.g. fume hoods) to prevent exposure to harmful fumes and vapors
- provision of personal protective equipment such as safety glasses, chemical resistant gloves, laboratory coats, respirators, face masks, and air monitors
- maintenance of a clean, uncluttered workspace
- specialized emergency equipment stations
- chemical disposal and destruction facilities and procedures
- specialized evidence receipt, storage and disposal requirements designed to mitigate expected dangers (e.g. limited sample size, proper packaging of reactive materials, use of absorbents, properly ventilated storage)

IIIC.2.4 Analysts shall be aware of the hazards associated with clandestine laboratories samples. Examples are:

- extracting from strong acids and bases (e.g. hydriodic acid, sodium hydroxide)
- handling fuming acids and bases (e.g. hydrochloric acid, ammonia)
- poisonous gases (e.g. phosphine, chlorine, hydrogen sulfide) and their potential release from evidence during analysis
- poisonous, carcinogenic, and mutagenic materials (e.g. mercuric chloride, chloroform, potassium cyanide)
- reactive and air sensitive materials (e.g. white phosphorus, lithium)
- potential testing incompatibilities (e.g. phosphorus with Raman, color test reagents with cyanide salts, exothermic reactions)
- radioactive materials (e.g. thorium)

- volatile and flammable solvents (e.g. acetone, diethyl ether, methylated spirits)

IIIC.3 Sample selection for analysis

IIIC.3.1 The primary purpose of analysis is to prove or disprove allegations of clandestine drug syntheses. Accordingly, analysts must select items which relate to the manufacturing process.

IIIC.3.2 Not all items seized at a clandestine laboratory site may need to be analyzed. It is recommended that information be shared between the analyst and on-scene personnel to aid in sample selection.

IIIC.3.3 Items should be selected for analysis, based on jurisdictional requirements, and which are likely to contain:

- finished product
- intermediates
- precursors
- key reagents
- reaction mixtures

IIIC.3.4 Some of the following types of items may be analyzed as they can assist in determining the chemical reaction(s) undertaken and the scope of the clandestine laboratory:

- materials that appear to be waste
- unlabeled materials that appear to be contaminated solvents, acids, or bases
- samples from contaminated equipment

IIIC.3.5 Items that are readily obtained from local retail stores and are sold from reputable manufacturers/distributors may not need to be analyzed, particularly if collected from sealed and labeled containers. These include:

- solvents (e.g. toluene, mineral spirits)
- acids (e.g. hydrochloric acid, sulfuric acid)
- bases (e.g. sodium hydroxide, ammonia water)

IIIC.4 Analysis

IIIC.4.1 Substances whose presence are reported or contribute to formulating reported conclusions shall be identified with an adequate analytical scheme.

IIIC.4.2 Where possible, the identification of organic compounds shall follow the recommendations for the analysis of seized drugs (see Part III B – Analytical Scheme for Identification of Drugs or Chemicals).

IIIC.4.3 The selectivity of analytical techniques for the identification of inorganic materials depends on the particular analyte. In each case the analytical scheme shall:

- have sufficient selectivity to identify the material to the exclusion of others (e.g. identification of both the cation and anion in salts)
- utilize two or more techniques, preferably from different analytical groups described below

IIIC.4.4 The following list of analytical groups and techniques are in no particular order and are not exhaustive. Analytical techniques must be selected which provide sufficient selectivity for each analyte. Some techniques may not be useful for particular analytes and each must be evaluated to determine suitability.

IIIC.4.4.1 Analytical Group 1: Elemental Analysis Techniques – these techniques may provide positive results for elements present in a sample but typically require additional tests to distinguish forms (e.g. oxidation state).

- Atomic Absorption Spectroscopy
- Atomic Emission Spectroscopy and Flame Tests (an attached spectrometer significantly increases the selectivity relative to flame tests)
- Energy Dispersive X-Ray Detectors for Scanning Electron Microscopes (SEM-EDX)
- Mass Spectrometry (utilizing Inductively Coupled Plasma sources or for elements with unique isotopic abundance patterns)
- X-Ray Fluorescence (XRF)

IIIC.4.4.2 Analytical Group 2: Structural Elucidation Techniques – these techniques may have high selectivity for polyatomic analytes.

- Infrared Spectroscopy (IR and FTIR)
- Mass Spectrometry
- Nuclear Magnetic Resonance (NMR)
- Raman Spectroscopy
- UV-Vis & Fluorescence Spectroscopy

IIIC.4.4.3 Analytical Group 3: Separation Techniques – these techniques can be valuable for mixtures and for distinguishing different forms of an element (e.g. phosphate and phosphite).

- Capillary Electrophoresis
- Gas Chromatography
- Ion Chromatography
- Liquid Chromatography
- Thin Layer Chromatography

IIIC.4.4.4 Analytical Group 4: Chemical Properties – These techniques involve observations of chemical changes. Utilizing several of these techniques, in series or combination, can often increase selectivity.

- Flammability
- Microcrystalline tests
- pH (of liquids or vapors)
- Radioactive decay
- Reactivity with water, air, or other materials
- Solubility and miscibility tests
- Spot and precipitation tests

IIIC.4.4.5 Analytical Group 5: Physical Properties – These techniques involve observations of physical properties. The selectivity of these techniques depends on the measuring device.

- Color
- Crystal forms measured with polarized light microscopy or x-ray diffraction techniques
- Density (relative density and density of mixtures have reduced selectivity)
- Phase transitions including melting points, boiling points, sublimation temperature and vapor pressure
- Physical state or states
- Refractive index
- Viscosity and surface tension

IIIC.4.5 If limited or qualified conclusions are sufficient (e.g. basic aqueous layer, non-polar organic solvent, a material containing the element phosphorus), tests of limited selectivity may be utilized within an analytical scheme.

IIIC.4.6 Analytical reference materials may not be available for the analysis of intermediates and byproducts. In these cases, samples taken from a test reaction in conjunction with suitable reference literature may be used for comparison purposes.

IIIC.4.7 Quantitative measurements of clandestine laboratory samples have an accuracy which is dependent on sampling and, if a liquid, on volume calculations. Accordingly, these measurements and calculations may be based on estimates. Under these conditions, a rigorous calculation of measurement uncertainty is often not possible or necessary and the uncertainty may best be conveyed by using a qualifier statement on the report (e.g. approximately, not to exceed, no less than).

IIIC.5 Yield and capacity calculations

IIIC.5.1 Yield and capacity calculations can be achieved from a number of approaches and shall be based on relevant case information, suitable literature, laboratory and jurisdictional requirements.

IIIC.5.2 Reported yields and capacities shall be based upon information documented in the laboratory case file.

IIIC.5.3 Calculated yields can be expressed as theoretical or expected.

IIIC.5.3.1 SWGDRUG recommends that reported yields be accompanied with an explanation clarifying the limitations or considerations.

IIIC.5.3.1.1 Theoretical yields are calculated based on the amount of known chemical, the stoichiometry of the reaction used in the clandestine laboratory and the product. Theoretical yields are not achievable in practice and their reporting can be misinterpreted.

IIIC.5.3.1.2 Expected yields are calculated based upon published data, experience, or practical experimentation. Expected yields can be highly variable based upon the factors listed below.

IIIC.5.4 In calculating expected yields and capacities in clandestine laboratories, many different sources of information can be used. Each case is different and will have a different set of evidence from which to draw information, including, but not limited to:

- amounts of finished products, precursors, or essential chemicals present
- amount of waste present
- size of reaction vessels and equipment
- volume and quantity of containers
- type / quantity of equipment and chemicals used
- state of equipment and premises (e.g. cleanliness of site and equipment)
- the apparent skill and laboratory practice of the operator
- the procedures (i.e. recipe) followed by the operator

IIIC.5.5 In addition to observations about the clandestine laboratory site itself, other pieces of evidence can lead to an understanding of yields and capacities, including, but not limited to:

- length of time the laboratory has been in operation
- intercepted conversations
- statements made by the clandestine laboratory operator during an interview/interrogation
- documents describing purchases of equipment, precursors, or reagents
- photographs of the clandestine laboratory site and other related areas.
- records kept by the clandestine laboratory operator (e.g. seized recipes or records of previously manufactured quantities)

IIIC.5.6 When calculating capacity, ensure that the values were not obtained from the same source (e.g. empty blister packs and tablet waste).

IIIC.6 Reports and conclusions

IIIC.6.1 Communications and reports, either written or verbal, shall be based upon all of the available and relevant information and with clearly stated assumptions and conditions.

IIIC.6.2 There are many facets to a clandestine laboratory investigation, such as:

- the illicit drug being made
- the synthetic route being utilized
- the type of equipment found at the site
- the past/potential production at the site
- the final form of the illicit drug
- the batch size at the site
- whether a tableting / encapsulating operation was present

IIIC.6.3 Factors to consider in determining what to report include, but are not limited to:

- jurisdictional requirements
- governing body (agency) requirements
- customer requests
- potential exculpatory information
- samples / analytes which represent the multiple stages in a reaction process

IIIC.6.4 Laboratories should have documented policies establishing protocols for reviewing verbal information and conclusions should be subject to technical review whenever possible. It is acknowledged that responding to queries in court or investigative needs may present an exception.

IIIC.6.5 When technical reviews are conducted, the individual reviewing the conclusions must be knowledgeable in the processing, analysis, and reporting of clandestine laboratory seizures.

IIIC.7 Training

IIIC.7.1 Analysis and interpretation of a clandestine laboratory case requires specialized skills. The main objective of clandestine laboratory training programs should be to provide new analysts with a sound education in the fundamental areas of clandestine laboratory evidence analysis. These recommendations assume the student is qualified as a seized drug analyst.

IIIC.7.2 Analysts shall receive training which will enable them to safely perform the analysis of clandestine drug laboratory samples.

IIIC.7.3 Analysts shall receive training which will enable them to assist in investigation of clandestine drug syntheses. Aspects of this training may include:

- chemical separation techniques (e.g. acid/base extractions, ion pair extractions, precipitation)
- production estimates
- study of pertinent drug syntheses by various routes
- training on intermediates and route specific by-products
- knowledge of common and alternative sources of chemicals
- training in inorganic chemistry, analysis techniques, and interpretation
- common terminology used in organic chemistry and synthesis

- application of critical thinking and problem solving skills to the evaluation of all case information (e.g. officer and scene reports, recipes, chemical data)
- the ability to recognize when additional information is required, identify sources for that information (journals, monographs, underground references), critically evaluate the reference and apply that knowledge to case information
- legal issues and courtroom testimony

IIIC.7.4 Analysts should stay current in the field of clandestine drug manufacturing and clandestine laboratory investigations. Examples of this element include:

- joining regional, national, and international scientific organizations
- attending conferences specializing in clandestine drug manufacture
- receiving training by qualified instructors covering current trends and reviews
- reading pertinent scientific literature
- monitoring relevant illicit literature and sites

PART III D

METHODS OF ANALYSIS/ANALOGUES AND STRUCTURAL CLASS DETERMINATIONS

IIID.1 Introduction

IIID.1.1 This section provides general recommendations regarding analogues and structural class determinations.

IIID.1.2 Jurisdictional requirements for such determinations may include structural or pharmacological (real or purported) similarity to known controlled substances or structural class definitions.

IIID.1.3 SWGDRUG considers it fundamental for analysts to fully understand how analogues and structural classes are legally defined in a particular jurisdiction and the applicable elements of their local legislative requirements prior to developing or reporting opinions.

IIID.1.4 Such opinions should only be rendered by those with proper training and experience, as defined by laboratory procedures.

IIID.2 Analogues

IIID.2.1 The requirements for legal consideration as a controlled substance analogue are defined in jurisdictional legislation.

IIID.2.2 Classification as a controlled substance analogue generally involves the evaluation of the similarity of structure or pharmacological properties of a chemical compound to a known controlled substance.

IIID.2.3 The scientific evaluation of similarity may be made using a variety of techniques and approaches depending on the specific question being addressed. These specific comparisons can be broadly classified by structure, chemical properties, biochemical or pharmacological activity.

IIID.2.4 The laboratory shall have a written procedure regarding structural similarity determinations, which shall include a description of the factors to be considered during the comparison and how each shall be documented in the case file.

IIID.2.5 The documentation of the evaluation of similarities between chemical compounds shall include a discussion of how the compounds are similar and how they are different.

IIID.2.5.1 Evaluation of similarity is a subjective matter and opinions may differ.

IIID.2.5.2 Structural comparisons in a forensic laboratory may be limited to the structural class and functional group, ring or chain substitutions. As examples, isomers, homologues, salt forms, atomic substitutions, esters, and ethers may be considered. The scope of comparison conducted should be made clear in the report.

IIID.2.6 Structural similarity between two chemical compounds is not an adequate basis to infer similar pharmacological activity, e.g. naloxone and hydromorphone.

IIID.2.7 Likewise a lack of structural similarity is not an adequate basis to infer a lack of analogous pharmacological activity, e.g. fentanyl and morphine.

IIID.2.8 If pharmacological activity is a requirement of particular legislation and drug analysts are asked for such information by the judge or presiding authority, they should not provide such testimony in the absence of specific training and experience in pharmacology (or related fields). Should the drug analyst cite peer-reviewed literature, they shall qualify the limitations of their expertise.

IIID.3 Structural Class Determinations

IIID.3.1 In many jurisdictions, chemical compounds are controlled based upon structural class definitions (e.g., 3-(1-naphthoyl)indole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl ring to any extent).

IIID.3.2 A structural class determination may be made by identifying a specific compound and assigning the compound as a member of a legally defined structural class.

IIID.3.3 The laboratory shall have a written procedure for structural class determinations, which should include the documentation requirements for the assignment of the unknown to a structural class.

IIID.3.4 The analytical scheme employed must satisfy all structural requirements of the structural class definition, e.g. where substitutions are, types of substitutions.

IIID.3.5 A structural class determination may also be made using an analytical scheme designed to identify sufficient features of a compound to assign it as a member of a legally defined structural class without making a conclusive identification of that compound (e.g., ortho, meta, or para position of a halogen on an aromatic ring).

IIID.3.6 Relevant limitations of the analytical scheme and resulting classification shall be clear in reporting, e.g. The powder was analyzed and found to contain a chemical in the legally defined chemical class Amphetamine, specifically (2, 3, or 4)-fluoroamphetamine.

IIID.4 Reporting

IIID.4.1 All conclusions and opinions expressed in written or oral form shall be based on sufficient supporting evidence, data, or information, as defined by laboratory procedures.

IIID.4.2 The basis of any conclusion should be completely documented in the case notes and summarized in the written report and subject to the laboratory's review policy. It is acknowledged that responding to queries in court or investigative needs may present an exception.

IIID.4.3 Conclusions and opinions reported shall be accurate, clear, and meet the jurisdictional requirements. The report must also include any relevant assumptions or limitations (e.g. potentially exculpatory information), to allow the court to make the final decision.

IIID.4.4 The report should clearly indicate what elements of the legal requirements were evaluated and what elements were not evaluated.

IIID.4.5 The scope of opinions and conclusions reported, in either written or oral form, shall not go beyond the knowledge, training and experience of the analyst.

PART IV A

QUALITY ASSURANCE/GENERAL PRACTICES

IVA.1 Introduction

It is the goal of a laboratory's drug analysis program to provide the customers of the laboratory's services access to quality drug analysis. It is the goal of these recommendations in PART IV A to provide a quality framework for management of the processing of drug casework, including handling of evidentiary material, management practices, qualitative and quantitative analysis and reporting. These are minimum recommendations for practice.

The term “evidence” has many meanings throughout the international community. In this document, it is used to describe drug exhibits that enter a laboratory system.

IVA.2 Quality management system

A documented quality management system shall be established and maintained. The quality management system shall consider the risks and opportunities of the laboratory activities to reduce potential failures and achieve improvements.

IVA.2.1 Personnel responsible for this shall be clearly designated and shall have direct access to the highest level of management concerning laboratory policy.

IVA.2.2 The quality management system shall cover all procedures and reports associated with drug analysis.

IVA.3 Personnel

IVA.3.1 Job description

The job descriptions for all personnel should include responsibilities, duties and required skills.

IVA.3.2 Designated personnel and responsibilities

An individual (however titled) may be responsible for one or more of the following duties:

IVA.3.2.1 Technical Support Personnel: Individuals who perform basic laboratory duties, but do not analyze evidence.

IVA.3.2.2 Technician/Assistant Analyst: A person who analyzes evidence, but does not issue reports for court purposes.

IVA.3.2.3 Analyst: A designated person who:

a) examines and analyzes seized drugs or related materials, or directs such examinations to be done

b) independently has access to unsealed evidence in order to remove samples from the evidentiary material for examination AND

c) as a consequence of such examinations, signs reports for court or other purposes.

IVA.3.2.4 Technical Leader: A designated person who has the overall responsibility and authority for the technical operations of the drug analysis section. Technical operations include, but are not limited to protocols, analytical methodology, and technical review of reports.

IVA.3.2.5 Quality Assurance Manager: A designated person who is responsible for maintaining the quality management system (including an annual review of the program) and who monitors compliance with the program.

IVA.3.2.6 Health & Safety Manager: A designated person who is responsible for maintaining the Laboratory Health and Safety program (including an annual review of the program) and monitors compliance with the program.

IVA.3.3 Qualifications/Education

IVA.3.3.1 Technical Support Personnel shall

a) have education, skills and abilities commensurate with their responsibilities AND

b) have on-the-job training specific to their position.

IVA.3.3.2 Technicians/Assistant Analysts shall

a) have education, skills and abilities commensurate with their responsibilities AND

b) have on-the-job training specific to their position.

IVA.3.3.3 Analysts shall meet educational requirements stated in Part II – Education and Training (Section 2).

IVA.3.3.4 Technical Leaders shall

a) meet all the requirements of an analyst (3.3.3),

b) have a minimum of two (2) years of experience as an analyst in the forensic analysis of drugs and

c) demonstrate knowledge necessary to evaluate analytical results and conclusions.

IVA.3.4 Initial training requirements

Initial training requirements for analysts are defined in Part II – Education and Training (Section 3).

IVA.3.5 Maintaining competence

Continuing professional development for analysts is defined in Part II – Education and Training (Section 4).

IVA.4 Physical plant

IVA.4.1 Laboratories shall provide a healthy, safe and secure environment for its personnel and operations.

IVA.4.2 Laboratories shall contain adequate space to perform required analytical functions and prevent contamination.

IVA.4.3 Chemical fume hoods shall be provided. They shall be properly maintained and monitored according to an established schedule.

IVA.4.4 A laboratory cleaning schedule should be established and implemented.

IVA.4.5 Adequate facilities shall be provided to ensure the proper safekeeping of evidence, standards and records.

IVA.4.6 Appropriately secured storage shall be provided to prevent contamination of chemicals and reagents.

IVA.5 Evidence control

Laboratories shall have and follow a documented evidence control system to ensure the integrity of physical evidence.

IVA.5.1 Receiving and identifying evidence

Laboratories shall maintain records of requests for analysis and of the respective items of evidence. For chain-of-custody purposes, the evidence shall be compared to the submission documentation, any significant observations of irregularity shall be documented in the case file or record, and the submitter informed promptly. This file or record shall include, at least, the following:

- submission documents or copies
- identity of party requesting analysis and the date of request
- description of items of evidence submitted for analysis
- identity of the person who delivers the evidence, along with date of submission
- for evidence not delivered in person, descriptive information regarding mode of delivery and tracking information
- chain of custody record
- unique case identifier.

IVA.5.2 Integrity of evidence

Evidence shall be properly secured (e.g., sealed). Appropriate storage conditions shall ensure that, insofar as possible, the composition of the seized material is not altered. All items shall be safeguarded against loss or contamination. Any alteration of the evidence (e.g. repackaging) shall be documented. Procedures shall be implemented to assure that samples are and remain properly labeled throughout the analytical process.

IVA.5.3 Storage of evidence

Access to the evidence storage area shall be granted only to persons with authorization and access shall be controlled. A system shall be established to document a chain of custody for evidence in the laboratory.

IVA.5.4 Disposition of evidence

Records shall be kept regarding the disposition (e.g., returned, destructed/consumed, converted to another use) of all items of evidence.

IVA.5.5 Documentation retention procedures

All laboratory records such as analytical results, measurements, notes, calibrations, chromatograms, spectra and reports shall be retained in a secure fashion in accordance with jurisdictional requirements.

IVA.6 Analytical procedures

IVA.6.1 Analytical procedures for drug analysis

IVA.6.1.1 Laboratories shall have and follow documented analytical procedures.

IVA.6.1.2 Laboratories shall have in place protocols for the sampling of evidence (see PART III A – Sampling).

IVA.6.1.3 Work practices shall be established to prevent contamination of evidence during analysis.

IVA.6.1.4 Laboratories shall have and follow documented guidelines for the acceptance and interpretation of data.

IVA.6.1.5 Laboratories shall monitor the analytical processes using appropriate blanks, controls and reference materials.

IVA.6.1.6 Reference materials and reference data are critical to demonstrating the validity of quantitative and qualitative test results. A positive test result shall meet the acceptance criteria defined in the method validation and operating protocol. In descending order of preference, SWGDRUG recommends that the acceptance criteria should be based on one of the following:

IVA.6.1.6.1 Comparison to data obtained from a suitable drug reference material analyzed under the same analytical conditions as the test/case sample. If reference material data are collected on a different instrument than the test/case sample, it must be demonstrated that both instruments produce comparable data.

The reference material may be analyzed:

- contemporaneously with test/case sample (e.g. same sequence/batch)
- as part of routine quality control (e.g. daily check solutions)

- at a previous date (e.g. method validation, internal reference collection)

IVA.6.1.6.2 Comparisons to external reference data may be used where a reference material is unavailable. External reference data shall be assessed and demonstrated to be fit for purpose. Factors to consider include

- Origin of the data
- Validation of the data
- Peer review of the data
- Comparability of analytical conditions

IVA.6.1.6.3 When neither reference materials nor external reference data are available, structural elucidation techniques may be employed providing the analyst has the appropriate skills for their interpretation. Such interpretations shall be made only by analysts competent in structural elucidation interpretation.

IVA.6.1.7 Analytical procedures shall be validated in compliance with Part IV B - Validation.

IVA.6.1.8 When analysts determine the identity of a drug in a sample, they shall employ quality practices to ensure the results correspond to the sample tested. (see Part III B – Analytical Scheme for Identification of Drugs or Chemicals)

IVA.6.2 Assessment of drug reference materials

ISO/IEC 17025 specifies that reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials (CRM). For seized drugs, this requirement is difficult to fulfil because the concept of traceability for drug standards is not internationally established and CRM's for drug analysis are not readily available or affordable.

Note: A certificate does not necessarily define a material as a CRM.

IVA.6.2.1 SWGDRUG recommends laboratories have a process for assessing that reference materials are fit for purpose.

IVA.6.2.1.1 The assessment and purpose of a reference material shall be documented. The

documentation shall include the name of the individual who performed the assessment, the date of assessment, verification test data, and details of all reference materials and reference data used.

IVA.6.2.2 To be fit for purpose, the reference material must meet the minimum specification defined in the validation

IVA.6.2.2.1 The assessment shall be done on each lot of reference material.

IVA.6.2.2.2 This assessment shall be completed prior to or alongside casework analysis as appropriate.

IVA.6.2.2.3 Reference materials shall only be used for the purpose defined by the laboratory. For example, a reference material may be deemed suitable for qualitative but not quantitative determinations.

IVA.6.2.3 Fit for purpose for qualitative work requires an assessment of chemical identity.

IVA.6.2.4 Fit for purpose for quantitative work requires an assessment of purity and/or concentration, as appropriate to the application and its associated uncertainty of measurement in addition to the parameters in 6.2.3.

IVA.6.2.4.1 For quantitative determinations, different sources of reference material should be used for calibration and quality control. Where this is not feasible, two different lots of the same source may be used or lastly a single source of reference material can be sub-divided and each part assigned a specific purpose.

IVA.6.2.5 These parameters in Sections 6.2.3 and 6.2.4 may be described in a certificate, statement of analysis, data sheet or label supplied with the material or may be determined by in-house analysis or reference to published literature.

IVA.6.2.6 The laboratory shall assess the reliability of the information supplied with a reference material even if the material meets the definition of a CRM.

IVA.6.2.6.1 For reference materials obtained from a provider accredited under ISO 17034, the information contained in the accompanying certificate is considered reliable and can be accepted as correct if the material is stored and used in accordance with the manufacturer's instructions. In these circumstances the assessment need not include analysis.

IVA.6.2.6.1.1 For reference materials obtained from a provider not accredited under ISO 17034, the identity and purity information supplied by the provider shall be verified by analysis. When verification by analysis is not possible, this shall be documented and, where applicable, the limitation expressed within the report. Other information may be evaluated as needed.

IVA.6.2.6.1.2 Examples of verification of chemical identity by analysis:

- Analysis and comparison of the results to peer-reviewed published data, data produced by a laboratory accredited under ISO/IEC 17025, or to data produced from a previously verified reference material.

- Evaluation of data from in-house structural elucidation analysis of the material.

IVA.6.2.6.1.3 Examples of verification of purity by analysis utilizing validated methods:

- Quantitative NMR Spectroscopy
- Quantitative UV-Visible Spectroscopy
- Comparison to previously verified material

IVA.6.2.6.2 Where a reference material has no or limited supporting documentation or is produced in-house (by synthesis or from a case sample),

then the chemical identity shall be determined in sufficient detail to demonstrate that it is fit for purpose. In addition, for quantitative work the purity and associated uncertainty of measurement shall also be determined.

IVA.6.2.7 Reference materials should have an expiration/retest date.

IVA.6.2.7.1 If the material is not supplied with an expiration date, one should be assigned at the first assessment (section 6.2.3, 6.2.4). If the expiration date passes before the material is fully used, then the material can be re-assessed and the expiration date extended.

IVA.6.2.7.2 The laboratory protocol for extending expiration dates shall be documented and should include analysis or, if applicable, re-analysis of the material.

IVA.6.2.7.3 If expiration dates are not assigned to reference materials, the laboratory must have a documented protocol for assessing the validity of the reference material each time it is used.

IVA.7 Instrument/Equipment performance

IVA.7.1 Instrument performance

IVA.7.1.1 Instrument performance shall be routinely monitored and documented to ensure that proper performance is maintained. Topics to consider when evaluating the need and frequency for intermediate checks include, but are not limited to, calibration interval, use of the equipment, stability of the equipment and risk associated with a failed check.

IVA.7.1.2 Monitoring shall include, at least, the use of blanks and reference materials, test mixtures, or calibration standards.

IVA.7.1.3 The manufacturer's operation manual and other relevant documentation for instrumentation should be readily available.

IVA.7.2 Equipment

IVA.7.2.1 Only suitable and properly operating equipment shall be employed.

IVA.7.2.2 Equipment performance parameters should be routinely monitored and documented.

IVA.7.2.3 The manufacturer's operation manual and other relevant documentation for each piece of equipment should be readily available.

IVA.8 Chemicals and reagents

IVA.8.1 Chemicals and reagents used in drug testing shall be of appropriate grade for the tests performed.

IVA.8.2 There shall be documented formulations for all chemical reagents produced within the laboratory.

IVA.8.3 Documentation for reagents prepared within the laboratory shall include identity, concentration (when appropriate), date of preparation, identity of the individual preparing the reagents, storage conditions (if appropriate) and the expiration date (if appropriate).

IVA.8.4 The efficacy of all reagents shall be checked prior to or concurrent with their use in casework. Results of these tests shall be documented.

IVA.8.5 The received date and opened date shall be recorded for chemicals and reagents, where relevant to testing results.

IVA.8.6 Chemical and reagent containers shall be labeled as to their contents.

IVA.9 Casework documentation, report writing and review

IVA.9.1 Casework documentation

IVA.9.1.1 Documentation shall contain sufficient information to allow a peer to evaluate case notes and interpret the data.

IVA.9.1.2 Evidence handling documentation shall include chain of custody, information regarding packaging of the evidence upon receipt, the initial weight/count of evidence to be examined (upon opening), a description of the evidence and communications regarding the case.

IVA.9.1.3 Analytical documentation should include procedures, standards, blanks, observations, test results and supporting

documentation including charts, graphs and spectra generated during an analysis.

IVA.9.1.4 Casework documentation shall be preserved according to documented laboratory policy.

IVA.9.2 Report writing

Reports issued by laboratories shall be accurate, clear, objective, and meet the requirements of the jurisdictions served.

These reports shall include the following information:

- title of report
- identity and location of the testing laboratory
- unique case identifier (on each page)
- clear identification of the end of the report (e.g., Page 3 of 3)
- submitting agency
- date of receipt of evidence
- date of report
- description of relevant evidence and unambiguous identification of tested items
- date(s) of performance of laboratory activity
- identity of analyst
- conclusions / results with, where appropriate, the units of measurement
- a list of analytical techniques employed
- additions to, deviations or exclusions from the method
- sampling plan or method (see Part III A - Reporting)
- a statement to the effect that the result relates only to the items tested or sampled
- uncertainty (see Part IV C - Uncertainty)
- clear identification when results are from external providers
- where relevant, a statement of conformity with requirements or specifications (e.g. statutory regulations)
- where appropriate, opinions and interpretations (e.g. clandestine laboratory synthetic route determination).

If elements listed above are not included on the report, the laboratory shall have documented reasons (i.e. specific accreditation, customer or jurisdictional considerations), for not doing so.

IVA.9.3 Case review

IVA.9.3.1 Laboratories shall have documented policies establishing protocols for technical and administrative case review.

IVA.9.3.2 Laboratories shall have a documented policy for resolving case review disagreements between analysts and reviewers.

IVA.10 Proficiency and competency testing

Each laboratory shall establish a documented competency testing and proficiency testing program. Each laboratory shall have documented protocols for monitoring the competency and proficiency of its analysts.

NOTE It is recognized that different jurisdictions may define competency and proficiency testing in a manner other than how they are used here. In this context, competency tests measure the ability of the analyst to produce accurate results. Proficiency tests are an ongoing process in which a series of proficiency samples, the characteristics of which are not known to the participants, are sent to laboratories on a regular basis. Each laboratory is tested for its accuracy in identifying the presence (or concentration) of the drug using its usual procedures.

IVA.10.1 Proficiency testing

IVA.10.1.1 Laboratories shall perform proficiency testing in order to verify the laboratory's performance. The frequency of the proficiency testing shall be, at least, annually. Where possible, at least one of these proficiency tests should be from an external proficiency test provider.

IVA.10.1.2 Proficiency test samples should be representative of the laboratory's normal casework.

IVA.10.1.3 The analytical scheme applied to the proficiency test should be in concert with normal laboratory analysis procedures.

IVA.10.2 Competency testing

IVA.10.2.1 Laboratories shall monitor the competency of their analysts annually (e.g. proficiency testing, observation of lab activities).

IVA.10.2.2 If competency test samples are utilized, they should be representative of the laboratory's normal casework.

IVA.10.2.3 The analytical scheme applied to the competency test should be in concert with normal laboratory analysis procedures.

IVA.11 Analytical method validation and verification

IVA.11.1 Method validation is required to demonstrate that methods are suitable for their intended purpose (see PART IV B – Validation).

IVA.12 Laboratory audits

IVA.12.1 Internal audits of laboratory operations shall be conducted at least once a year.

IVA.12.2 Records of each audit shall be maintained and include the scope, date of the audit, name of auditor(s), findings and any necessary corrective actions.

IVA.13 Deficiency of analysis

In the course of examining seized drug samples and related materials, laboratories may encounter some operations or results that are deficient in some manner. Each laboratory shall have a documented policy to address such deficiencies.

IVA.13.1 This policy shall include the following:

a) a definition of a deficiency as any erroneous analytical result or interpretation, or any unapproved deviation from an established policy or procedure in an analysis;

NOTE Deviations from established policy shall have documented management approval.

b) a requirement for immediate cessation of the activity or work of the individual involved, if warranted by the seriousness of the deficiency, as defined in the documented policy;

c) a requirement for administrative review of the activity or work of the individual involved;

d) a requirement for evaluation of the impact the deficiency might have had on other operations, equipment, materials, or laboratory personnel;

e) a requirement for documentation of the follow-up action taken as a result of the review including actions to reduce or prevent future deficiencies;

f) a requirement for communication to appropriate employees of any confirmed deficiency which may have implications for their work.

NOTE It should be recognized that to be effective, the definition for "deficiency of analysis" shall be relatively broad. As such, deficiencies may have markedly different degrees of seriousness. For example, a misidentification of a controlled substance would be very serious and perhaps require that either the methodology or the analyst be suspended pending appropriate remedial action, as determined by management. However, other deficiencies might be more clerical in nature, requiring a simple correction at the first-line supervisory review, without any suspension of methodology

or personnel. Thus, it may well be advantageous to identify the differing levels of seriousness for deficiencies and make the action required be commensurate with the seriousness.

IVA.14 Health and safety

Laboratories shall have a documented health and safety program in place which incorporates harm reduction and improvement opportunities.

IVA.14.1 Health and safety requirements

IVA.14.1.1 All personnel should receive appropriate health and safety training.

IVA.14.1.2 Laboratories shall operate in accordance with laboratory policy and comply with any relevant regulations.

IVA.14.1.3 Laboratory health and safety manual(s) shall be readily available to all laboratory personnel.

IVA.14.1.4 Safety Data Sheets shall be readily available to all laboratory personnel.

IVA.14.1.5 All chemicals, biohazards and supplies shall be stored and disposed of according to applicable government regulations and laboratory policy.

IVA.14.1.6 Safety hazards such as syringes, items with sharp edges or noxious substances should be so labeled and stored in appropriate containers.

IVA.15 Additional documentation

In addition to casework documentation, laboratories shall maintain documentation on the following topics:

- test methods / procedures for drug analysis
- reference materials (including source and verification)
- preparation and checks of reagents
- evidence handling protocols
- equipment calibration and maintenance
- equipment inventory (e.g., manufacturer, model, serial number, acquisition date)
- proficiency testing
- personnel training and qualifications
- quality assurance protocols and audits
- health, safety and security protocols

- validation data and results
- uncertainty (see PART IV C – Quality Assurance/Uncertainty)
- quality-related customer feedback, when received.

PART IV B

QUALITY ASSURANCE/VALIDATION OF ANALYTICAL METHODS

IVB.1 Introduction

IVB.1.1 Method Validation provides objective evidence that a method produces data that meet or exceed its stated scope and intended purpose.

IVB.1.1.1 Method validation occurs after a method is developed and documented, but before being used in casework.

IVB.1.1.2 Method validation is conducted on analytical methods. Analytical techniques, instruments, or instrumental files may be part of or used in an analytical method, but are not directly or independently validated.

IVB.1.1.3 A single analytical method may describe a complete analytical scheme or be one of several methods used in an analytical scheme.

IVB.1.2 Method Verification provides objective evidence that a validated analytical method demonstrates the expected level of performance in a new laboratory or on a new instrument that was not included in the validation testing.

IVB.1.2.1 Verification is only appropriate if:

IVB.1.2.1.1 the analytical method was previously validated and the method validation results are available for reference.

IVB.1.2.1.2 the validated analytical method is being used without significant modification.

IVB.1.2.2 If these conditions are not met, or the method is not found to perform as expected when compared to the method validation results, method verification is not appropriate and a method validation shall be performed.

IVB.1.3 Laboratory management is responsible for ensuring that the methods used when analyzing casework are validated / verified. Analysts and technical reviewers are responsible for understanding the scope and limitations of validated methods so they may evaluate if an application falls within the method's validated scope.

IVB.1.4 The results and the conclusions of the method validation or verification process shall be documented and retained.

IVB.1.5 Additional data on the method's performance after the validation is complete may be appended to the method validation (e.g. new or varied analytes, matrices, or environmental conditions).

IVB.1.6 If substantive changes or updates are made to a method, a supplemental validation demonstrating that the changes did not affect the performance of the method shall be conducted and additional documentation appended to the original validation report.

IVB.1.7 When a method is used outside of method or validation scope (deviation from the method) or a validated analytical method is not available:

IVB.1.7.1 Case documentation shall include sufficient quality control samples and quality assurance practices to independently demonstrate that the method used in casework generates reliable and accurate results.

IVB.1.7.2 The deviation from validated methods shall be documented.

IVB.1.7.3 If the same method deviation or modification is made regularly, the method shall be updated and a new method validation or amendment to the validation shall be performed.

IVB.2 Documentation

IVB.2.1 An analytical method validation report shall include the following elements:

IVB.2.1.1 Approval

This can be in the form of a cover page, cover letter or approval document. This document shall be:

IVB.2.1.1.1 Signed by the individual primarily responsible for the validation, affirming that the testing process demonstrated that the method meets or exceeds the performance criteria outlined in the method scope and that all known limitations of the method are described therein.

IVB.2.1.1.2 Technically reviewed and signed by qualified personnel, other than the individual in 2.1.1.1 The technical review should be conducted by a qualified individual not involved in the validation planning or testing when possible.

IVB.2.1.2 Analytical Method

A copy of the analytical method that is the subject of the validation.

IVB.2.1.2.1 If the method has been updated, both the current version of the method and the version used in the original validation process shall be available.

IVB.2.1.3 Validation Plan

A copy of the validation plan describing how the validation will be conducted and the scope of parameters to be evaluated during the validation process. If specific method performance is required, consider defining acceptance criteria for the applicable performance characteristics.

IVB.2.1.4 Personnel

A listing of the personnel involved in the validation process including the planning, collection of data, review and evaluation of data, and approval of the validation report.

IVB.2.1.5 Reagents, Reference Materials, and Equipment

A list of the equipment and chemicals used in the validation process. The manufacturer, purity or grade, and lot number shall be included for critical reagents and reference materials. Samples procured from case materials or other sources should include a description of the sample and reference to how it was verified prior to use. Metrological traceability shall be considered where applicable.

IVB.2.1.6 Evaluation of Performance

A discussion of the efficacy of the method by evaluating each performance characteristic identified in the validation plan (see IVB2.1.3). This should include a clear conclusion of whether the method is fit-for-purpose, supported by

primary data or literature references when appropriate.

IVB.2.1.7 Scope and Limitations

Document the scope and known or observed limitations of the method, inclusive of data, interferences, and the effect of variation in environmental conditions encountered during the validation process.

IVB.2.1.8 Quality Control and Acceptance Criteria

Establish quality control requirements and data acceptance criteria based on the performance of the method during the method validation.

IVB.2.1.9 Bibliography

A list of references to all citable sources used in the development or validation of the method. This should include notes from discussions with experts consulted during these processes.

IVB.2.1.10 Retention of Validation Data

The raw data generated during the validation process shall be retained, including notes, photographs, instrumental data, certificates of analysis, instrument reports, quality control data and analysis spreadsheets or databases. If it is not practical to include these data within the validation report, the validation report will reference where and how to access these data.

IVB.3 Performance Characteristics

Identify the performance characteristics that need to be evaluated to demonstrate that the method meets or exceeds the requirements of its stated scope. The specific performance characteristics that need to be evaluated and the acceptance criteria depend on the method, intended use of the method and the samples it is expected to handle. The validation shall include an evaluation of the minimum performance characteristics listed for qualitative or quantitative methods below, but may need to include additional criteria.

IVB.3.1 The Validation of Qualitative Methods shall include:

IVB.3.1.1 Selectivity - Investigate possible interferences.

IVB.3.1.1.1 Test a variety of reference materials to demonstrate that target analyte(s) can be distinguished from other compounds.

IVB.3.1.2 Precision - Investigate the consistency of test results.

IVB.3.1.2.1 Test the precision of the method initially and over an extended timescale. This timescale shall exceed the planned frequency of analyzing reference materials or replacing prepared reagents.

IVB.3.1.2.2 Test the precision of the method when different batches of reference materials or reagents are used and over the range of environmental conditions likely to be encountered during normal use (e.g. lab temperature and humidity).

IVB.3.1.2.3 If the method will be used routinely by more than one individual, evaluate the variability in results obtained by different individuals.

IVB.3.1.2.4 If the method will be operated using more than one of the same instrument, evaluate the effect of using different instruments.

IVB.3.1.2.5 If the method will be used in more than one laboratory, evaluate the reliability when used in different laboratories.

IVB.3.1.3 Operating range – Evaluate a range of sample concentrations or amounts that can be analyzed using the method.

IVB.3.1.3.1 Use experimental data to establish a detection limit or verify that reliable data is obtained at an administratively set reporting limit.

IVB.3.1.4 Matrix effects – Evaluate the impact of the sample matrix on the response of the target analyte(s).

IVB.3.1.4.1 Test sample matrices that may be encountered in casework to assess the method's ability to meet the selectivity, precision, and operating

range requirements.

IVB.3.1.5 Additional performance characteristics appropriate to the method scope may be included, as necessary. Examples include carryover or stability of analyte.

IVB.3.2 The Validation of Quantitative Methods shall include:

IVB.3.2.1 Selectivity as described for qualitative analysis in IVB.3.1.1.

IVB.3.2.2 Precision as described for qualitative analysis in IVB.3.1.2. This shall include assessment of both the qualitative result and the quantitative measurement.

IVB.3.2.3 Trueness - Evaluate the agreement of experimentally measured results with the true value of reference materials.

IVB.3.2.3.1 Test the trueness of the method for samples at different concentrations, different purities, and in different matrices.

IVB.3.2.4 Sensitivity, Linearity, and Operating Range - Evaluate the performance of the calibration model across a range of sample concentrations or amounts.

IVB.3.2.4.1 Establish the range over which the method's calibration model (linear or other) describes the observed instrument response with suitable linearity (or closeness of fit) and sensitivity. The validation should include concentration or sample amounts distributed across this range.

IVB.3.2.4.2 Use experimental data to establish a lower and upper limit of quantitation or verify that reliable data is obtained across an administratively set operating range.

IVB.3.2.4.3 The limit of detection shall be established if the laboratory permits threshold reporting below the lower limit of quantitation (e.g., THC present at less than 0.001 mg/mL).

IVB.3.2.5 Matrix Effects as described for qualitative analysis in IVB.3.1.4. This shall include assessment of the matrix impact on the response and thus the quantitation of the target analyte.

IVB.3.2.6 Additional performance characteristics appropriate to the method scope, as necessary. Examples include carryover or stability of analyte.

IVB.4 Reference Materials

IVB.4.1 Reference materials shall be of sufficient quality to effectively evaluate whether the method produces reliable results.

IVB.4.1.1 Suitable reference materials shall be used to establish data acceptance criteria including metrological traceability, where applicable. Reference materials should have a known or established purity. (See Part IVA – Assessment of Drug Reference Materials)

IVB.4.1.2 Certified Reference Materials or materials with traceable purity shall be used in evaluating method trueness and the suitability of calibration models.

IVB.4.1.3 Case samples or simulated case samples should also be used when evaluating precision and matrix effects. Data authenticating the content of these samples should be available for reference.

IVB.5 Quality Assurance

IVB.5.1 Applicable quality assurance practices from the laboratory's quality system shall be followed while performing method validation.

IVB.5.2 Method validation shall be supported by management with sufficient:

IVB.5.2.1 Staffing to adequately conduct and supervise the project.

IVB.5.2.2 Resources and time to allow for the collection of adequate data to determine if the method is fit for purpose.

IVB.5.3 Qualifications of Personnel

IVB.5.3.1 Personnel must have prior authorization to participate in the validation process. Personnel shall possess sufficient education, training, and expertise for the role they will play in the method validation.

IVB.5.3.1.1 The individual supervising the validation should have training or expertise in principles of

method validation, the analytical techniques employed in the method, and forensic laboratory quality practices.

IVB.5.3.2 Individuals who are not fully qualified for casework may participate in collecting data to evaluate ruggedness, but shall not be involved in the approval of validation data.

IVB.5.4 Quality Control and Uncertainty

IVB.5.4.1 Review of the method validation data set may provide valuable information needed for other quality assurance activities. The validation report approval process should include consideration of:

IVB.5.4.1.1 Whether current quality control practices are sufficient to demonstrate that the method continues to perform as expected or whether additional or modified quality control practices are required.

IVB.5.4.1.2 Whether the validation data can be used to determine a new or updated uncertainty estimate.

IVB.5.4.2 The method, the method's limitations, and any quality control considerations raised during the validation process shall be incorporated or addressed in the laboratory's quality system prior to use of the method in casework.

IVB.5.5 Responsibility for Quality Assurance

IVB.5.5.1 During evaluation of the proper use of methods, Analysts and Technical Reviewers shall be responsible for:

IVB.5.5.1.1 Understanding the scope and limitations relevant to the application of the method in the case.

IVB.5.5.1.2 Ensuring that samples fall within the scope of the methods used in their analysis.

IVB.5.5.2 For a court appearance, the Analyst shall be prepared to testify:

IVB.5.5.2.1 Regarding the limitations relevant to the appropriate application of the method(s) in the case.

IVB.5.5.2.2 To the method validation or verification report(s)

IVB.6 References

a) Validation of Compendial Procedures, United States Pharmacopeia (USP) 1225, 2024.
b) Verification of Compendial Procedures, United States Pharmacopeia (USP) 1226, 2024.
c) “Modules in a Forensic Science Process”, ILAC-G19:06/2022.
d) “Collaborative versus traditional method validation approach: Discussion and business case”, Forensic Science International: Synergy 2 (2020) 230-237.
e) “A fitness for purpose approach to validation and verification of analytical measurements”, Accreditation and Quality Assurance (2018) 23:219-229.
f) “General requirements for the competence of testing and calibration laboratories” ISO/IEC 17025:2017(E).
g) Accreditation Requirements for Forensic Testing and Calibration (2023), AR 3125, ANAB.
h) “A tutorial on the validation of qualitative methods: From the univariate to the multivariate approach”, Analytical Chimica Acta, 891 (2015) 62-72.
i) *The Fitness for Purpose of Analytical Methods, A Laboratory Guide to Method Validation and Related Topics*, EURACHEM Guide, 2014.
j) “Guidance for the Validation of Analytical Methodology and Calibration of Equipment used for Testing of Illicit Drugs in Seized Materials and Biological Specimens” UNODC, 2009.
k) Validation of Analytical Procedures: Text and Methodology Q2(R1), ICH Harmonised Tripartite Guideline, 2005, www.ich.org.
l) Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis, IUPAC Technical Report, Pure appl. Chem., Vol 74, No. 5, pp. 835-855 (2002).

PART IV C

Quality Assurance/Uncertainty

IVC.1 Introduction

This recommendation provides guidance on the concept of uncertainty and its application to the qualitative and quantitative analysis of seized drugs. In this context, uncertainty encompasses limitations of qualitative methods as well as numerical ranges as applied to quantitative analyses.

IVC.1.1 SWGDRUG considers an understanding of uncertainty to be fundamental to the interpretation and reporting of results.

IVC.1.2 The term “uncertainty” does not imply doubt; rather, its consideration provides assurance that results and conclusions from methods and analytical schemes are fit for purpose.

IVC.1.3 SWGDRUG recommends the concept of uncertainty be considered for all analytical results.

IVC.1.4 Laboratory management shall ensure that uncertainty be addressed through the provision of training, procedures and documentation.

IVC.1.5 Laboratory management should consider customer requirements which influence the application of uncertainty.

IVC.1.6 Benefits

The benefits of determining and understanding uncertainty include:

- Enhancing confidence through increased understanding of results
- Providing a mechanism to express the reliability of results
- Enabling the laboratory and customer to evaluate the fitness for purpose of results
- Facilitating the identification of procedural limitations and providing a basis for improvement
- Complying with accreditation requirements.

IVC.1.7 Application of uncertainty

Qualitative and quantitative analyses require different approaches. Analysts shall understand the limitations of qualitative and quantitative determinations and have tools to estimate a value for measurement uncertainty of relevant, but not necessarily all, numerical results. In this regard, efforts should be made to use the vocabulary, symbols,

and formatting expressed in documents published by a Standards Developing Organization (SDO) such as ISO and ASTM International.

IVC.2 Qualitative Analysis

The identification of seized drugs requires the combination of methods to form an analytical scheme (see Part III B - Analytical Scheme for Identification of Drugs or Chemicals).

IVC.2.1 Individual methods have limitations and, consequently, uncertainty. Uncertainty of qualitative methods is not typically expressed in numerical terms.

IVC.2.2 Understanding these limitations enables the laboratory or analyst to build an appropriate analytical scheme to correctly identify a drug or chemical.

IVC.2.2.1 A reliable and scientifically supported identification of a drug or chemical depends on the use of an appropriate analytical scheme by competent analysts in a quality-controlled process.

IVC.2.2.2 Relevant limitations of an analytical scheme (e.g., inability to differentiate isomers, unavailability of reference material) should be documented and may need to be included in the report (see Part IV C - Reporting Examples).

IVC.3 Quantitative Measurements

IVC.3.1 Quantitative measurements have an associated uncertainty, which is defined as a parameter that “characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement or characteristic subject to test” (see Glossary).

IVC.3.2 A rigorous calculation of measurement uncertainty is not always required.

IVC.3.2.1 A laboratory shall understand the contributing factors of measurement uncertainty for each analytical procedure and evaluate them with respect to customer, accreditation or jurisdictional requirements.

IVC.3.2.2 Where a value is critical, such as a weight or purity level close to a statutory threshold, an appropriate measurement uncertainty estimation shall be applied.

IVC.3.3 Primary numerical values reported in the analysis of seized drugs are weight and purity. Where other values are measured (e.g., size, volume, estimated tablet numbers), the same principles stated herein apply.

IVC.4 Estimation of measurement uncertainty for quantitative determinations

IVC.4.1 Sources of uncertainty for weight determination

IVC.4.1.1 The uncertainty of a reported value is dependent on the weighing process. Factors for consideration include:

- Single versus multiple items (number of weighing operations)
- Taring of a weighing vessel as a separate weighing operation
- Extrapolation of population weight from limited sampling of multiple items
- Aggregate weighings
- Incomplete recovery of material from the packaging
- Balance selection (e.g., readability, capacity, calibration uncertainty)
- Balance operation (e.g., sample placement on pan, environmental conditions).

IVC.4.1.2 For further information and examples of estimation of measurement uncertainty for weight determinations, see Supplemental Document SD-3 (Measurement Uncertainty for Weight Determinations in Seized Drug Analysis).

IVC.4.2 Sources of uncertainty for purity determination

The uncertainty of a reported purity value is dependent upon the entire quantitation process. Factors for consideration include:

- Sampling plan (e.g., handling of multiple exhibits)
  - Sample homogeneity
- Analytical method
  - Sample preparation (e.g., sample size, matrix effects, solubility)
  - Analytical technique
  - Reference material (e.g., purity of standard)
  - Equipment and instrument properties (e.g., glassware, pipettors, balances, chromatographs)
  - Concentration of analyte
  - Environmental conditions.

IVC.4.3 Factors relevant to estimation of measurement uncertainty

IVC.4.3.1 When estimating measurement uncertainty, the following sources of error shall be considered:

IVC.4.3.1.1 Analytical Error: Systematic and random error both contribute to measurement uncertainty and shall be addressed through method validation and quality assurance practices (Part IV B). SWGDRUG recommends that for all validated procedures, systematic error is characterized and minimized.

IVC.4.3.1.2 Sampling Error: The sample and sampling procedure are often the greatest contributors to measurement uncertainty.

IVC.4.3.2 Where appropriate, confidence levels (e.g., 95% or 99.7%) shall be selected based on considerations relevant to the analytical context.

IVC.4.3.3 Uncertainty information shall be recorded in validation documents and/or case records.

IVC.4.4 Approaches for estimating measurement uncertainty

IVC.4.4.1 Uncertainty budget approach

IVC.4.4.1.1 In this approach all sources of error are separately identified and tabulated.

IVC.4.4.1.2 A value is assigned to each source of error (collectively or individually) using either:

- empirical data (e.g., from validation process, historical performance data, control chart data, proficiency tests)
- published data (e.g., volumetric glassware tolerances)
- combination of empirical and published data.

NOTE: Control chart data, including measurement quality assurance, should be derived from multiple data points over time and is expected to capture the typical variations of realistic laboratory processes.

IVC.4.4.1.3 Where a source has an uncertainty which is insignificant compared to other sources, it can be excluded.

IVC.4.4.1.4 The remaining significant values are used to calculate the combined standard uncertainty and expanded uncertainty.

IVC.4.4.2 Non-budget approaches

IVC.4.4.2.1 The sources of uncertainty that are separately assessed in the budget method are collectively assessed by experimental measurement. In this approach data obtained from a statistically significant number of replicate analyses utilizing a validated method with an appropriate sampling plan may be utilized to calculate the standard or expanded uncertainty.

IVC.4.4.2.2 An alternate approach involves the use of two standard deviations (2σ) of the test method results from reproducibility data from the validation studies. This provides an approximation of the measurement uncertainty for non-critical values.

IVC.5 Reporting of uncertainty

IVC.5.1 Reporting

Uncertainty shall be reported when it may impact the use of a result by the customer, unless the laboratory has documented reasons (i.e. specific accreditation, customer or jurisdictional considerations), for not doing so. Factors which influence the decision to report uncertainty include:

IVC.5.1.1 Jurisdictional

- Prevailing statutory requirement
- Relevant governing body (agency) requirements
- Customer requests
- Potential exculpatory value

IVC.5.1.2 Types of Analysis

- Qualitative: Qualitative results where limitations of analytical scheme are known and relevant (e.g., inability to differentiate isomers, unavailability of reference material)
- Quantitative: Quantitative measurements where a value is critical (e.g., weight or purity level close to a statutory threshold)

IVC.5.1.3 Laboratory accreditation requirements

IVC.5.2 Reporting Examples

Reporting requirements and styles differ among agencies. The examples listed below are drawn from laboratories with varied requirements.

IVC.5.2.1 Qualitative Results

IVC.5.2.1.1 Contains ephedrine or pseudoephedrine. Item tested: 5.2 grams net.

IVC.5.2.1.2 Visual examination determined that the physical characteristics are consistent with a Schedule IV pharmaceutical preparation containing Diazepam. There was no apparent tampering of the dosage units and no further tests are being conducted.

IVC.5.2.1.3 Contains cocaine (salt form not determined)

IVC.5.2.2 Quantitative Results

Factors to be considered when reporting measurement uncertainty include use of significant figures, confidence intervals and rounding/truncating of results.

IVC.5.2.2.1 Active drug ingredient (established or common name) methamphetamine hydrochloride
Gross weight: 25.6 grams
Net weight: 5.2 grams
Conc. or purity: 54.7% (± 2.8%)*
Amount of actual drug: 2.8 grams
Reserve weight: 5.1 grams

* This value represents the quantitative uncertainty measurement estimate for the laboratory system.

IVC.5.2.2.2 Positive for cocaine in the sample tested
Net weight of total sample: 5.23 grams ± 0.03 grams
Quantitation: 54.7% ± 2.8%

IVC.5.2.2.3 Sample tested positive for cocaine

Net weight: 5.23 grams
Purity: 54.7%
Confidence Range: ± 2.8%*
Calculated net weight of drug: 2.8 grams of cocaine

*Confidence range refers to a 95% confidence level.

IVC.5.2.2.4 Cocaine was identified in the Item 1 powder at a purity of 65 ± 9% (99.7% confidence level). The Item 1 powder weighed 800 ± 4 mg (99.7% confidence level).

IVC.5.2.2.5 White powder: 5.6 grams
The range of heroin concentration identified in the sample was not less than 53.2% and not more than 56.2%.

IVC.6 Training

IVC.6.1 Individuals responsible for determining, evaluating and documenting uncertainty in the context of seized-drug analysis shall be capable of competently demonstrating familiarity with foundational concepts and principles of estimating uncertainty.

IVC.6.1.1 Useful topics to review include:

- General metrology to include: terminology, symbols, formulae, publications, international organizations, and global application as related to seized-drug analysis
- The concepts of random and systematic error, accuracy, precision (repeatability, reproducibility, and their conditions), statistical control, standard and expanded uncertainty, correlation and propagation of error
- Reporting conventions including use of significant figures, truncation and rounding
- Basic statistics (descriptive and inferential) to include: measures of central tendency (e.g., median), measures of variation, statistical modeling, sampling, probability, confidence interval, and significance level

IVC.6.2 All analysts shall be capable of explaining their laboratory's procedures for evaluating uncertainty of qualitative and quantitative analyses.

IVC.7 References

IVC.7.1 Eurachem/CITAC Guide: *The Expression of Uncertainty in Qualitative Testing*, Committee Draft September 2003.

IVC.7.2 *GUM, Evaluation of measurement data — Guide to the expression of uncertainty in measurement Published by the Joint Committee for Guides in Metrology (JCGM), JCGM 100:2008.*

IVC.7.3 *Guidelines for Evaluation and Expressing the Uncertainty of NIST Measurement Results*, National Institute of Standards and Technology, NIST Technical Note 1297, 1994 Edition.

IVC.7.4 *General requirements for the competence of testing and calibration laboratories* International Organization for Standardization, ISO/IEC 17025: 2005.

IVC.7.5 *Guide for the use of the International System of Units (SI)*, Taylor, B.N., National Institute of Standards and Technology, April 1995.

IVC.7.6 *Standard Practice of Using Significant Digits in Test Data to Determine Conformance with Specifications*, ASTM E29, West Conshohosken, PA.

IVC.7.7 *Quantifying Uncertainty in Analytical Measurements*, Eurachem, 2000, 2nd ED.

IVC.7.8 *Experimental Statistics*, M. Natrella, National Bureau of Standards (NBS), USA 1966.

IVC.7.9 ISO 3534-1 *Statistics — Vocabulary and symbols Part 1: General statistical terms and terms used in probability*, ISO 3534-2 *Statistics — Vocabulary and symbols Part 2: Applied statistics* International Organization for Standardization, Switzerland, 2006.

IVC.7.10 ISO Guide 99:2007 *The International Vocabulary of Basic and General Terms in Metrology*, International Organization for Standardization, Switzerland, 2007.

IVC.7.11 ISO 5725-1 *Accuracy (Trueness and Precision) of Measurement Methods and Results Part 1: General Principles and Definitions* International Organization for Standardization, Switzerland,1994.

IVC.7.12 *The Uncertainty of Measurements. Physical and Chemical Metrology Impact and Analysis.* Kimothi, S.K., Milwaukee: American Society for Quality, 2002.

IVC.7.13 *Fundamentals of Analytical Chemistry*, 8th Edition, Skoog**,** D.A., *et al.* Brooks Cole, 2003.

IVC.7.14 *Measurement Uncertainty Arising from Sampling: A Guide to Methods and Approaches. Eurachem/CITAC Guide, 1st edition, 2007.*

IVC.7.15 ASTM E2655 *Standard Guide for Reporting Uncertainty of Test Results and Use of the Term Measurement Uncertainty in ASTM Test Methods.*

ANNEX A

SWGDRUG GLOSSARY OF TERMS AND DEFINITIONS

A.1 Introduction

This glossary of terms and definitions has been developed and adopted by the SWGDRUG core committee from a variety of sources that are listed in endnotes. In some instances, the core committee modified existing definitions or created definitions where none could be found in standard references.

Definitions containing the term NOTE typically derive from conformance standards. The NOTE portion of the definition serves to clarify a point, but is not intended to be a requirement. In the glossary where DISCUSSION is used, the associated text serves to fill in more detail of the concept being defined. These are included as a reader-friendly supplement.

A.2 Terms and definitions

A.2.1 accuracy

closeness of agreement between a test result or measurement result and the true value

NOTE 1 In practice, the accepted reference value is substituted for the true value.
NOTE 2 The term “accuracy”, when applied to a set of test or measurement results, involves a combination of random components and a common systematic error or bias component.
NOTE 3 Accuracy refers to a combination of trueness and precision.

[ISO 3534-2:2006]

A.2.2 analyst

a designated person who:

- examines and analyzes seized drugs or related materials, or directs such examinations to be done,
- independently has access to unsealed evidence in order to remove samples from the evidentiary material for examination and,
- as a consequence of such examinations, signs reports for court or other purposes

[SWGDRUG]

A.2.3 analytical method

the technique (e.g. gas chromatography, color test, infrared spectroscopy) and associated operating parameters, reagent preparations, sample preparation steps, and data evaluation steps that are required for an analysis.

DISCUSSION - A qualitative method detects or identifies the specified analyte(s). A quantitative method determines the amount of analyte(s) present with an associated measurement uncertainty.

[SWGDRUG]

A.2.4 analytical scheme

a combination of selected techniques (qualitative, quantitative, or both) used to reach a result, comprised of validated methods that are appropriate for the analyte(s) being identified. [SWGDRUG]

A.2.5 analyte

the component of a system to be analyzed

[IUPAC]

A.2.6 audit

systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled

[ISO 9000:2005 (E)]

A.2.7 bias

the difference between the expectation of the test results and an accepted reference value.

[ASTM E 177-06b, ASTM E456-06]

DISCUSSION - For a measurement laboratory, bias is the difference (generally unknown) between a laboratory's average value (over time) for a test item and the average that would be achieved by the reference laboratory if it undertook the same measurements on the same test item.

[NIST/SEMATCH e-Handbook of Statistical Methods]

A.2.8 blank

specimen or sample not containing the analyte or other interfering substances

[Modified UNODC Definition]

A.2.9 byproduct

a secondary or incidental product of a manufacturing process.

[Collins English Dictionary - Complete & Unabridged 10th Edition]

A.2.10 calibration

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

NOTE 1 A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.
NOTE 2 Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.

[VIM 2008]

A.2.11 calibration curve

the mathematical relationship that exists between the analyte concentration or sample amount and the signal produced by an analytical technique, over a selected range of concentrations.

[SWGDRUG]

A.2.12 capacity

the amount of finished product that could be produced, either in one batch or over a defined period of time, and given a set list of variables.

[SWGDRUG]

A.2.13 carryover

unintended analyte signals that are detected in later tests that can originate from previously analyzed samples or reference materials.

[SWGDRUG]

A.2.14 catalyst

a substance whose presence initiates or changes the rate of a chemical reaction, but does not itself enter into the reaction.

[ASTM-D6161]

A.2.15 certified reference material (CRM)

reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

NOTE 1 The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.
NOTE 2 Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guides 34 and 35.
NOTE 3 ISO Guide 31 gives guidance on the contents of certificates.
NOTE 4 VIM has an analogous definition (ISO/IEC Guide 99:2007, 5.14).

[ISO GUIDE 30:2008]

A.2.16 chain of custody
procedures and documents that account for the integrity of a specimen or sample by tracking its handling and storage from its point of collection to its final disposition
[UNODC]

A.2.17 clandestine
secret and concealed, often for illicit reasons.
[Collins English Dictionary - Complete & Unabridged]

A.2.18 combined standard uncertainty
standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariances of these other quantities weighted according to how the measurement result varies with changes in these quantities
[GUM 2008]

A.2.19 control
material of established origin that is used to evaluate the performance of a test or comparison
[ASTM E1732-09]

A.2.20 deficiency of analysis
any erroneous analytical result or interpretation, or any unapproved deviation from an established policy or procedure in an analysis
[SWGDRUG]

A.2.21 detection limit
see A.2.29 *limit of detection*

A.2.22 equipment
Set of laboratory tools, apparatus, and hardware used to process test items (for example, ovens, beakers, pipettes, vortexers, fume hoods, etc.)
[ASTM 3255-21]

A.2.23 expanded uncertainty (U)
quantity defining an interval about a result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand

NOTES
1. The fraction may be regarded as the coverage probability or level of confidence of the interval.
2. To associate a specific level of confidence with the interval defined by the expanded uncertainty requires explicit or implicit assumptions regarding the probability distribution characterized by the measurement result and its combined standard uncertainty. The level of confidence that may be attributed

to this interval can be known only to the extent to which such assumptions can be justified.

3. An expanded uncertainty U is calculated from a combined standard uncertainty u_c and coverage factor k using: $U = k \times u_c$

[EURACHEM, GUM 2008]

A.2.24 false negative

Test result that states that an analyte is absent, when, in fact, it is present above the established limit of detection for the analyte in question

[SWGDRUG]

A.2.25 false positive

test result that states that an analyte is present, when, in fact, it is not present or, is present in an amount less than a threshold or designated cut-off concentration

[SWGDRUG]

A.2.26 finished product

a manufactured product ready for use.

[SWGDRUG]

A.2.27 instrument

Equipment capable of performing measurements used to generate analytical data (for example, GC-MS, IR, NMR, balances, etc.)

[ASTM 3255-21]

A.2.28 intermediate

substance that is manufactured for and consumed in or used for chemical processing to be transformed into another substance.

[ASTM- F2725]

A.2.29 limit of detection

The lowest analyte concentration or sample amount that can be reliably differentiated from the blank matrix or instrument noise.

[SWGDRUG]

A.2.30 limit of quantitation

the lowest concentration of an analyte that can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test

[EURACHEM]

A.2.31 linearity
The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample.

[ICH, 2005]

DISCUSSION: In cases where linearity is not applicable, the closeness of fit and suitability of non-linear calibration models should be assessed.

[SWGDRUG]

A.2.32 matrix effect
the combined effect of all components of the sample other than the analyte on the measurement of the quantity. If a specific component can be identified as causing an effect then this is referred to as interference.

[IUPAC Gold Book]

A.2.33 method validation
a process of empirically testing and evaluating objective evidence to assess the strengths and limitations of a method, and to establish whether requirements for an intended use or application have been fulfilled.

[SWGDRUG]

A.2.34 method verification
confirmation through empirical testing and evaluation of objective evidence that a previously validated method performs as expected.

[SWGDRUG]

A.2.35 performance characteristic
Property of an analytical method that describes its capabilities.

DISCUSSION: Examples of performance characteristics include selectivity and precision.

[SWGDRUG]

A.2.36 pharmaceutical identifiers
physical characteristics of tablets, capsules or packaging indicating the identity, manufacturer, or quantity of substances present

[SWGDRUG]

A.2.37 population
the totality of items or units of material under consideration

[ASTM E456-06]

A.2.38 precision

closeness of agreement between independent test/measurement results obtained under stipulated conditions

NOTE 1 Precision depends only on the distribution of random errors and does not relate to the true value or the specified value.
NOTE 2 The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results or measurement results. Less precision is reflected by a larger standard deviation.
NOTE 3 Quantitative measures of precision depend critically on the stipulated conditions. Repeatability conditions and reproducibility conditions are particular sets of extreme stipulated conditions.

[ISO 3534-2:2006]

DISCUSSION - precision is evaluated under various stipulated conditions including repeatability (short-term precision), ruggedness (intermediate precision), and reproducibility (long-term precision) conditions.

[SWGDRUG]

A.2.38.1 Repeatability (short term precision)

the closeness of agreement between results obtained with the same method in the same laboratory by the same operator using the same equipment within short intervals of time.

[SWGDRUG]

A.2.38.2 Ruggedness (intermediate precision)

the closeness of agreement between results obtained with the same method on identical test items in the same laboratory over time, and under a variety of conditions, operators, equipment, calibrations, or batch of reagents.

[SWGDRUG]

A.2.38.3 Reproducibility (long term precision)

the closeness of agreement between results obtained with the same method over extended time. This may include changed conditions such as different laboratories, different operators, or different equipment.
DISCUSSION: other definitions of reproducibility require measurements to occur in different laboratories; however, in the context of the SWGDRUG recommendations, reproducibility can be evaluated at one location in the case of a single-laboratory system.

[SWGDRUG]

A.2.39 precursor

a chemical that is transformed into another compound, as in the course of a chemical reaction, and therefore precedes that compound in the synthetic pathway. [Webster's Unabridged Dictionary of the English Language]

A.2.40 procedure
specified way to carry out an activity or process

NOTES

1. Procedures can be documented or not.
2. When a procedure is documented, the term “written procedure” or “documented procedure” is frequently used. The document that contains a procedure can be called a “procedure document.”

[ISO 9000:2005 (E)]

A.2.41 proficiency testing
ongoing process in which a series of proficiency specimens or samples, the characteristics of which are not known to the participants, are sent to laboratories on a regular basis. Each laboratory is tested for its accuracy in identifying the presence (or concentration) of the drug using its usual procedures. An accreditation body may specify participation in a particular proficiency testing scheme as a requirement of accreditation.

[UNODC]

A.2.42 qualitative analysis
analysis in which substances are identified or classified on the basis of their chemical or physical properties, such as chemical reactivity, solubility, molecular weight, melting point, radiative properties (emission, absorption), mass spectra, nuclear half-life, etc.

See also A.2.44 *quantitative analysis*

[IUPAC]

A.2.43 quality assurance
part of quality management focused on providing confidence that quality requirements will be fulfilled.

[ISO 9000:2005 (E)]

A.2.44 quality management
coordinated activities to direct and control an organization with regard to quality

NOTE Direction and control with regard to quality generally includes establishment of the quality policy and quality objectives, quality planning, quality control, quality assurance and quality improvement.

[ISO 9000:2005 (E)]

A.2.45 quality manual
document specifying the quality management system of an organization

NOTE Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.

[ISO 9000:2005 (E)]

A.2.46 quantitative analysis

analyses in which the amount or concentration of an analyte may be determined (estimated) and expressed as a numerical value in appropriate units. Qualitative analysis may take place without quantitative analysis, but quantitative analysis requires the identification (qualification) of the analytes for which numerical estimates are given

[IUPAC]

A.2.47 random sample

the sample so selected that any portion of the population has an equal (or known) chance of being chosen. Haphazard or arbitrary choice of units is generally insufficient to guarantee randomness

[IUPAC]

A.2.48 range

the analyte concentration or sample amount limits for which the method is applicable; this is also referred to as the operating range.

[SWGDRUG]

A.2.49 reagent

a chemical used to react with another chemical, often to confirm or deny the presence of the second chemical.

[ASTM-E1605]

A.2.50 recovery

proportion of the amount of analyte, present in or added to the analytical portion of the test material, which is extracted and presented for measurement.
[Harmonized Guidelines for the use of recovery information in analytical measurement, IUPAC]

A.2.51 reference material (RM)

material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process

NOTE 1 RM is a generic term.
NOTE 2 Properties can be quantitative or qualitative, e.g. identity of substances or species. NOTE 3 Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.
NOTE 4 A single RM cannot be used for both calibration and validation of results in the same measurement procedure.

NOTE 5 VIM has an analogous definition (ISO/IEC Guide 99:2007, 5.13), but restricts the term
“measurement” to apply to quantitative values and not to qualitative properties. However, Note 3 of ISO/IEC Guide 99:2007, 5.13, specifically includes the concept of qualitative attributes, called “nominal properties”.

[ISO GUIDE 30:2008]

A.2.52 reliability, statistical
consistency of results as demonstrated by reproducibility or repeatability

[OSAC Lexicon]

A.2.53 repeatability (short-term precision)
see A.2.38.1 under *precision*

A.2.54 reproducibility (long-term precision)
see A.2.38.3 under *precision*

A.2.55 robustness
a measure of an analytical method’s capacity to remain unaffected by small variations in method parameters.

[SWGDRUG]

A.2.56 ruggedness (intermediate precision)
see A.2.38.2 under *precision*

A.2.57 sample
subset of a population made up of one or more sampling units

NOTE 1 The sampling units could be items, numerical values or even abstract entities depending on the population of interest.
NOTE 2 The definition of sample in ISO 3534-2 includes an example of a sampling frame which is essential in drawing a random sample from a finite population.

[ISO 3534-1:2006(E/F)]

A.2.58 sampling
act of drawing or constituting a sample

[ISO 3534-2:2006]

A.2.59 sampling plan
a specific plan which states the sample size(s) to be used and the associated criteria for accepting the lot

NOTES

1. A criterion is, for example, that the number of nonconforming items is less than or equal to the acceptance number.
2. The sampling plan does not contain the rules on how to take the sample.

[ISO 3534-2:1993 (E/F)]

A.2.60 sampling procedure

operational requirements and/or instructions relating to the use of a particular sampling plan; i.e., the planned method of selection, withdrawal and preparation of sample(s) from a lot to yield knowledge of the characteristic(s) of the lot

[ISO 3534-2:1993 (E/F)]

A.2.61 sampling scheme

a combination of sampling plans with rules for changing from one plan to another

NOTE Some schemes have switching rules for automatic change to tightened inspection plans or reduced inspection plans or change to 100 % inspection.

[ISO 3534-2:1993 (E/F)]

A.2.62 scope of method

The expected purpose and use of a method including the types of samples (e.g. matrix, concentration purity), a summary of the techniques used, and the types and quality of results generated. [SWGDRUG]

A.2.63 selectivity

Refers to the extent to which a method can determine particular analyte(s) in a complex mixture without interference from the other components in the mixture. A method which is perfectly selective for an analyte or group of analytes is said to be specific. The term specific (in analysis) is considered as the ultimate of selectivity.

[UNODC, October 2009, ISBN 978-92-1-148243-0]

A.2.64 sensitivity

(a) Difference in analyte concentration corresponding to the smallest detectable difference in the response of the method. It is represented by the slope of the calibration curve. Sometimes it is used, erroneously, to mean detection limit.

(b) Incidence of true positive results obtained when a test is applied to samples known to contain the analyte.

(c) Change in the response of a measuring instrument divided by the corresponding change in the stimulus. The stimulus may, for example, be the amount of the measurand present.

[UNODC]

A.2.65 standard uncertainty

uncertainty of the result of a measurement expressed as a standard deviation

[GUM 2008]

A.2.66 traceability

ability to trace the history, application or location of that which is under consideration

NOTES

1. When considering product, traceability can relate to
   - the origin of materials and parts,
   - the processing history, and
   - the distribution and location of the product after delivery.
2. In the field of metrology the definition in VIM:1993, 6.10, is the accepted definition.

[ISO 9000:2005 (E)]

A.2.67 trueness

closeness of agreement between the expectation of a test result or a measurement result and a true value

NOTE 1 The measure of trueness is usually expressed in terms of bias.

NOTE 2 Trueness is sometimes referred to as “accuracy of the mean”. This usage is not recommended. NOTE 3 In practice, the accepted reference value is substituted for the true value.

[ISO 3534-2:2006]

A.2.68 uncertainty (measurement)

parameter, associated with the measurement result, or test result, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement or characteristic subject to test

NOTE 1 This definition is consistent with VIM but differs from it in phrasing to fit into this part of ISO 3534 concepts and to include the testing of characteristics.

NOTE 2 “Parameter” is defined in ISO 3534-1. The parameter can be, for example, a standard deviation or a given multiple of it.
NOTE 3 Uncertainty of measurement or test comprises, in general, many components. Some of these components can be estimated on the basis of the statistical distribution of the results of a series of measurements and can be characterized by standard deviations. Other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.
NOTE 4 Components of uncertainty include those arising from systematic effects associated with corrections and reference standards which contribute to the dispersion.
NOTE 5 Uncertainty is distinguished from an estimate attached to a test or measurement result that characterizes the range of values within which the expectation is asserted to lie. The latter estimate is a measure of precision rather than of accuracy and should be used only when the true value is not defined. When the expectation is used instead of the true value, the expression “random component of uncertainty” is used.

[ISO 3534-2:2006]

A.2.69 validation
see A.2.33 *method validation*

A.2.70 verification
see A.2.34 *method verification*

A.2.71 yield, expected
the quantity of material or the percentage of theoretical yield anticipated at any appropriate phase of production based on previous laboratory, pilot scale, or manufacturing data.

[ASTM-E2363]

A.2.72 yield, theoretical
the quantity that would be produced at any appropriate phase of production based upon the quantity of material to be used, in the absence of any loss or error in actual production.

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